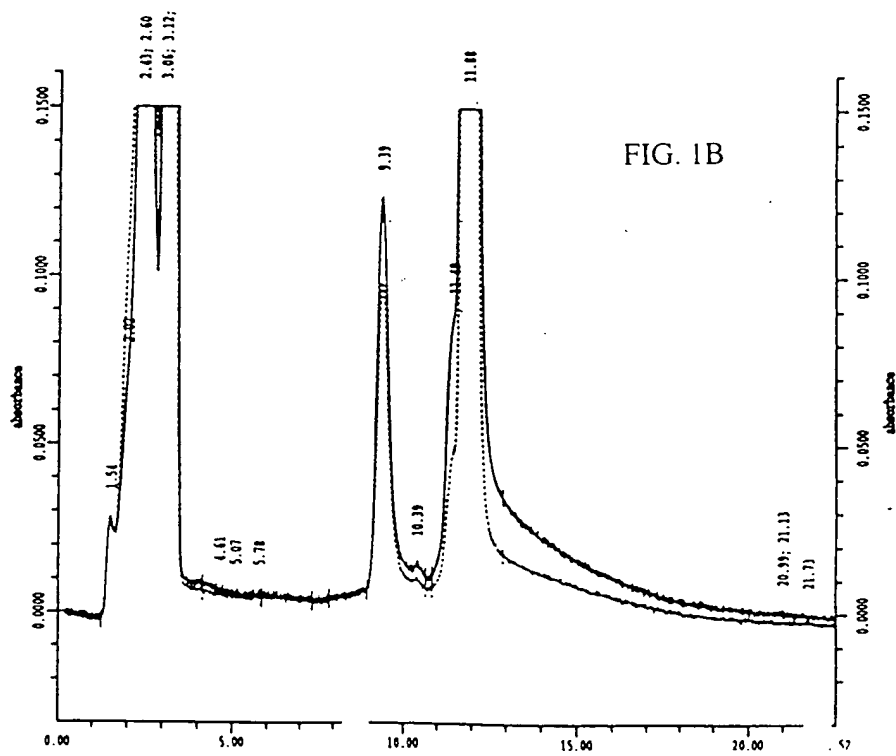
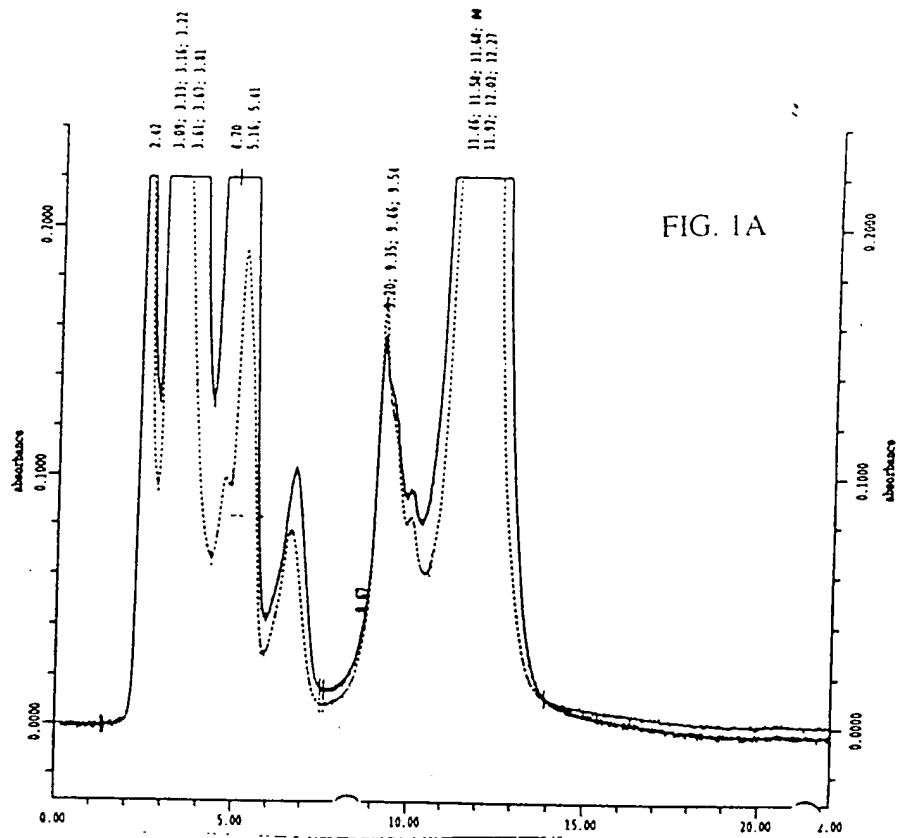


09203078 120198



09203078-1203

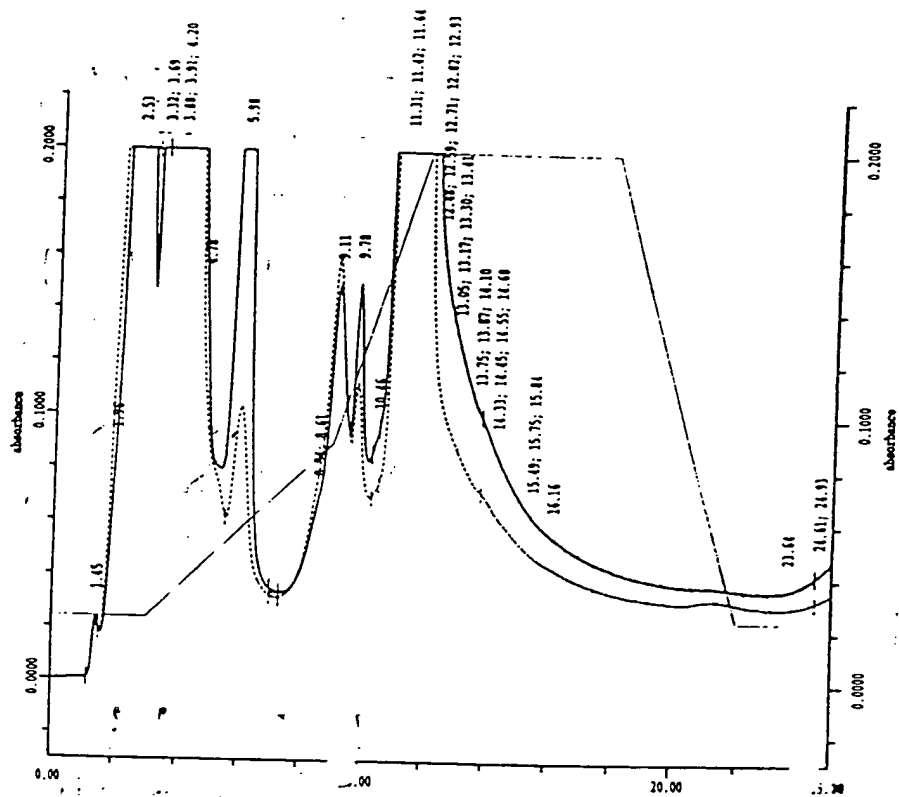
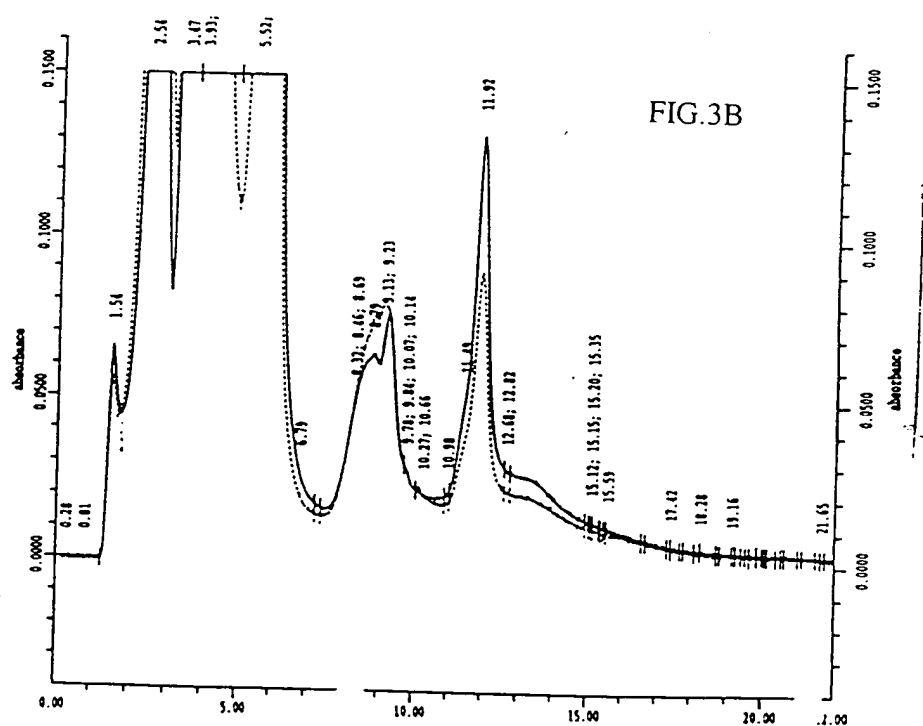
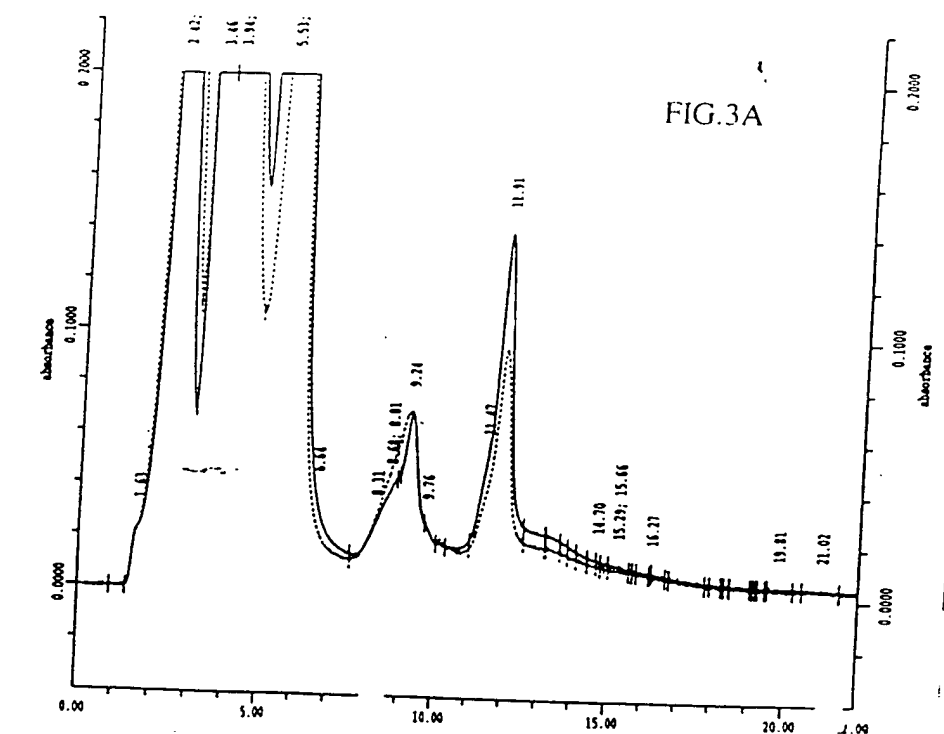


FIG. 2



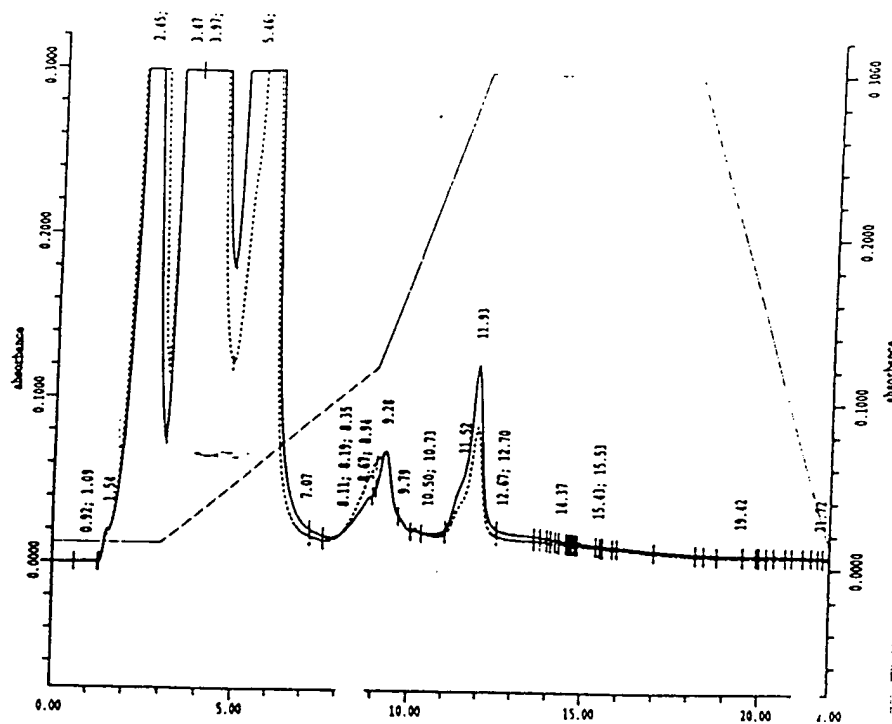


FIG.3C

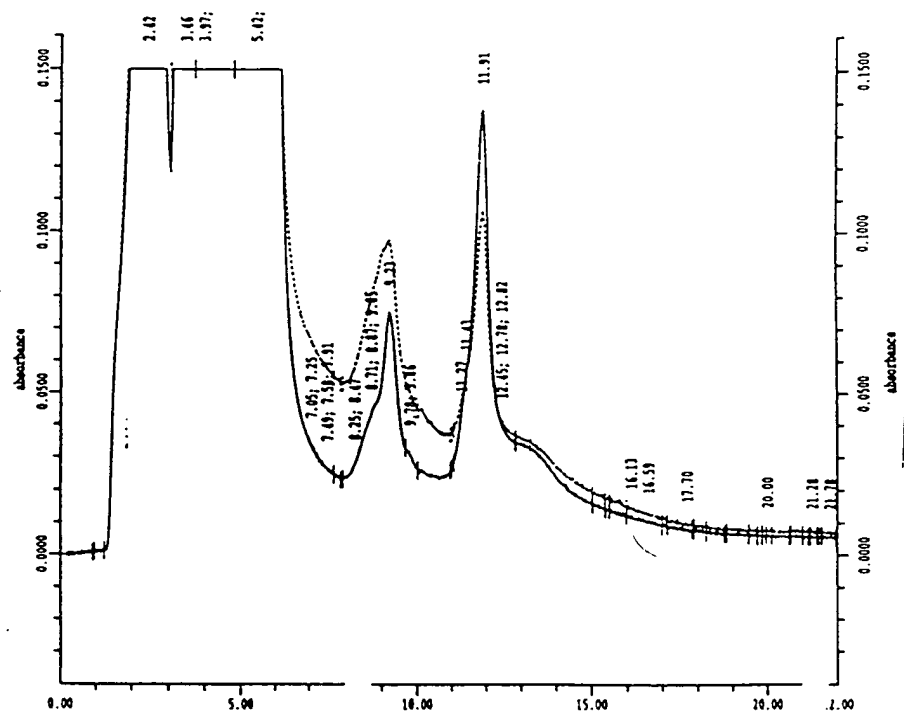


FIG.3D

09203078.120198

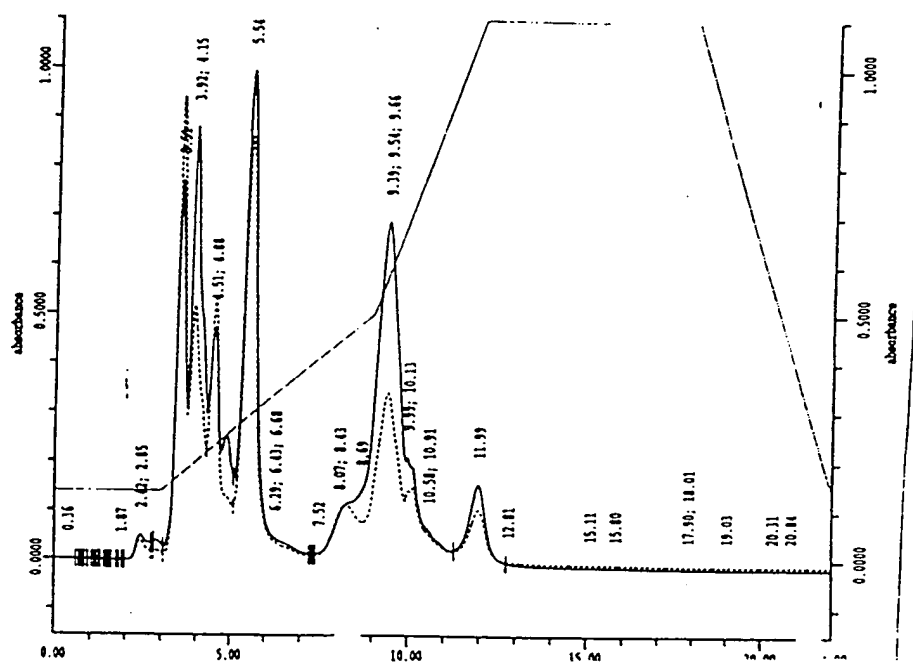
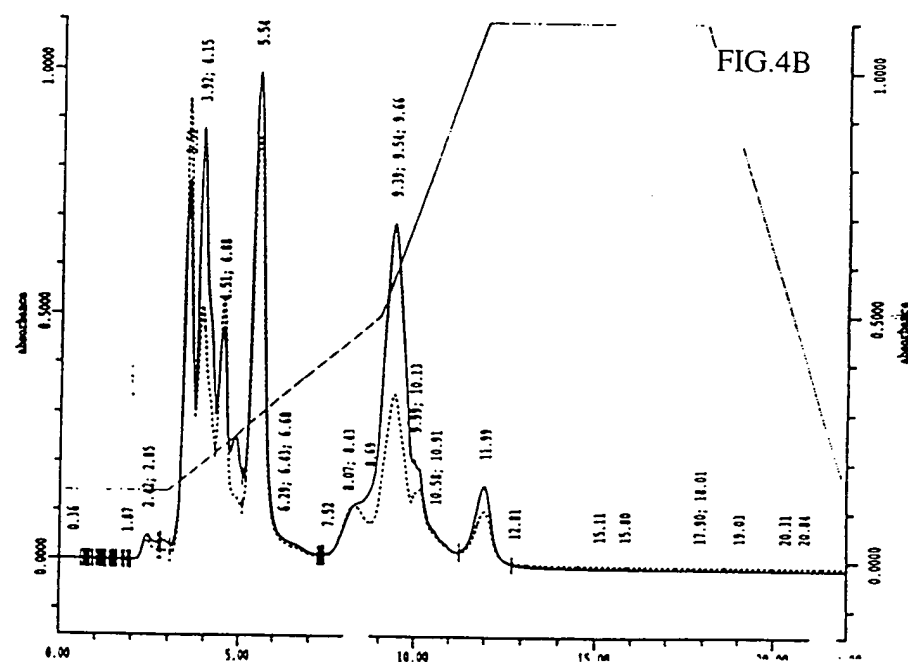
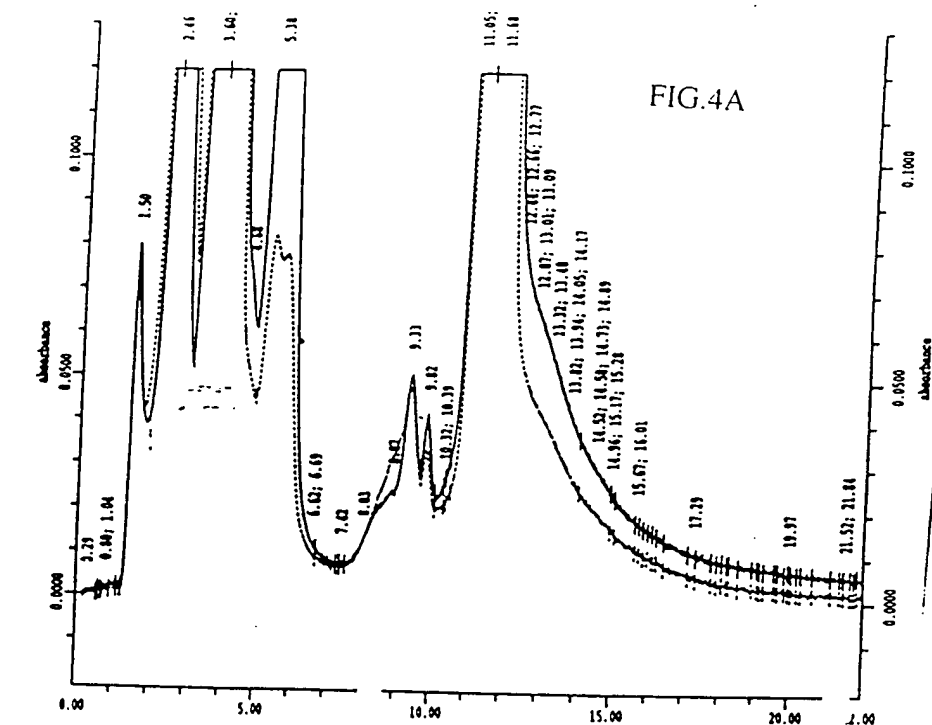


FIG.3E



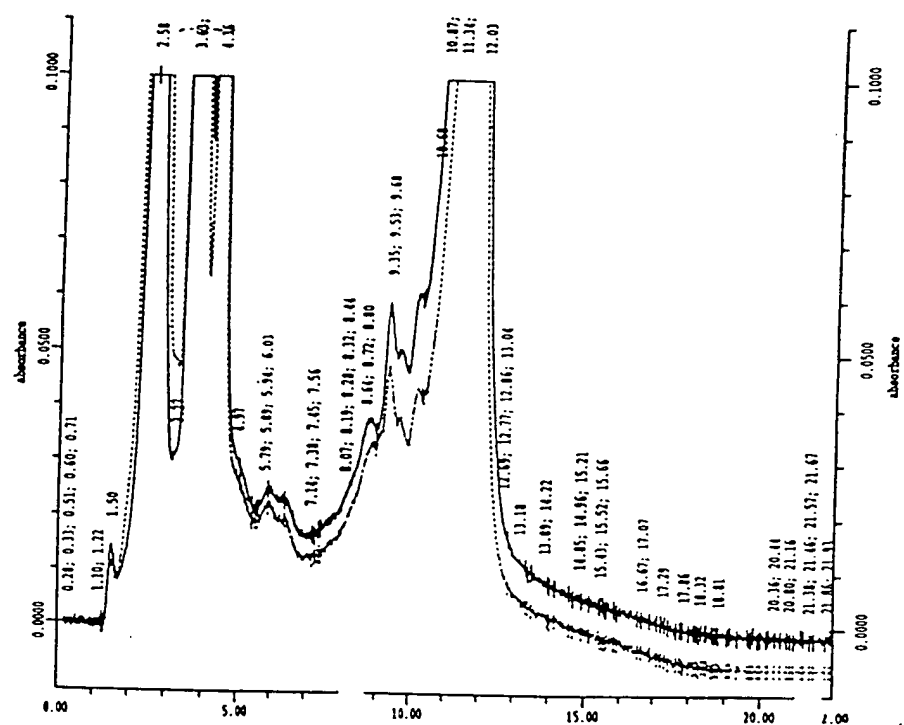


FIG.5

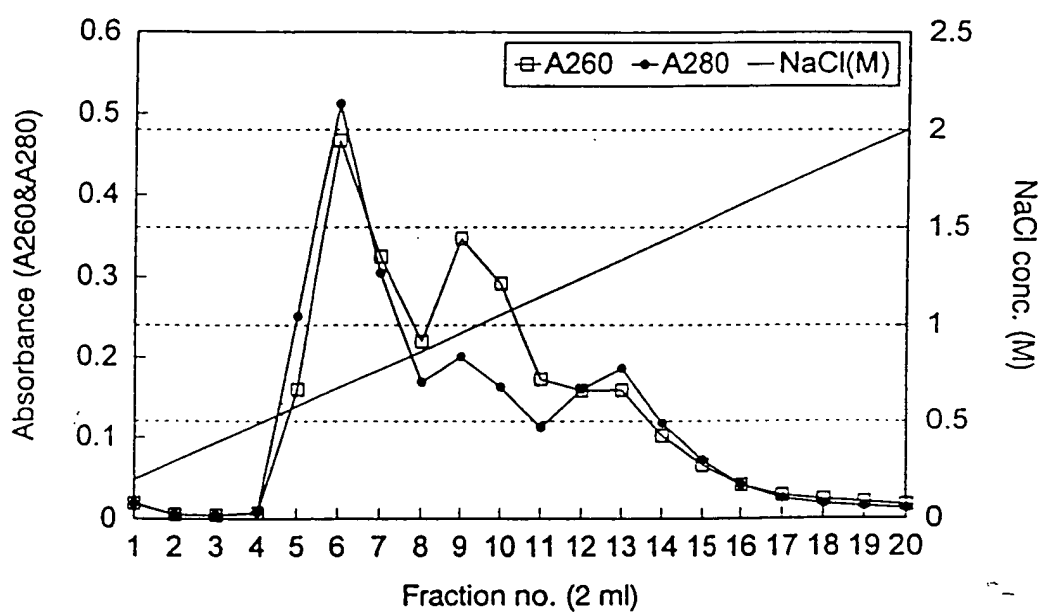


FIG.6

09203078-120198

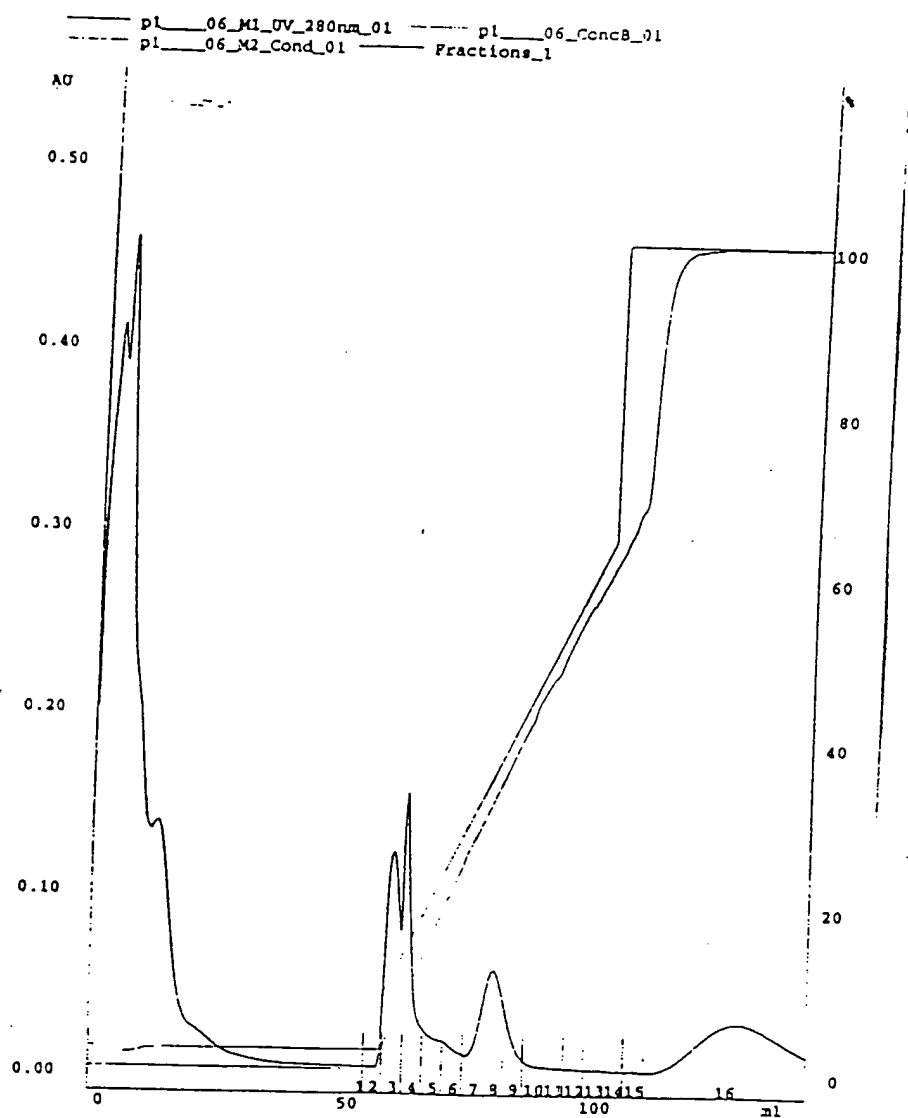
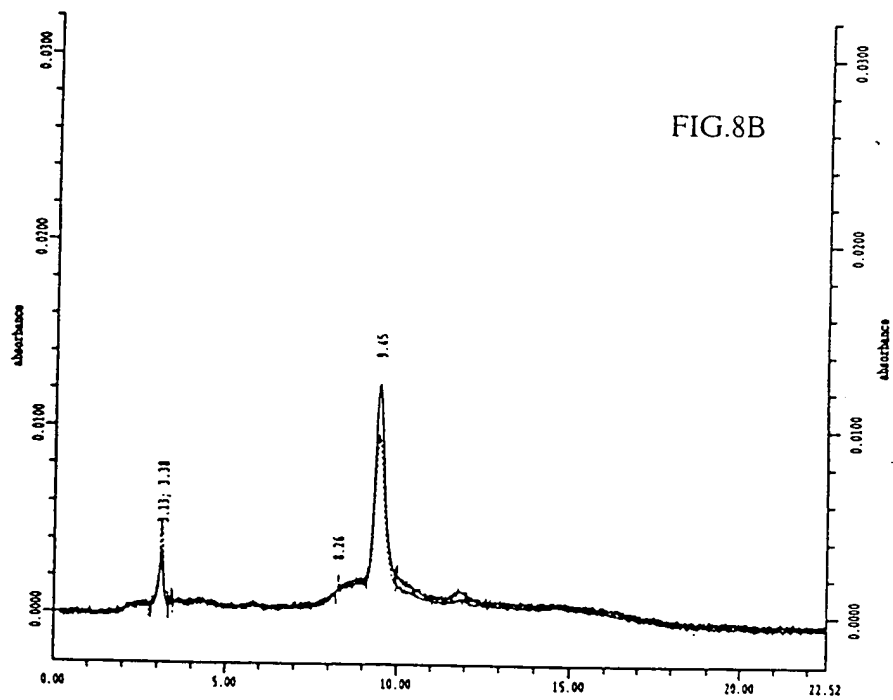
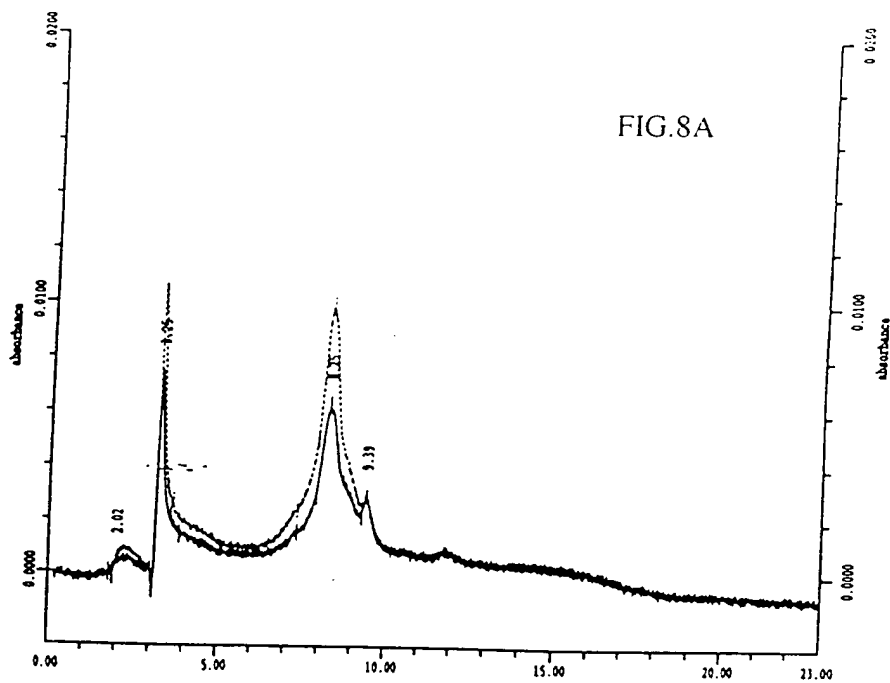
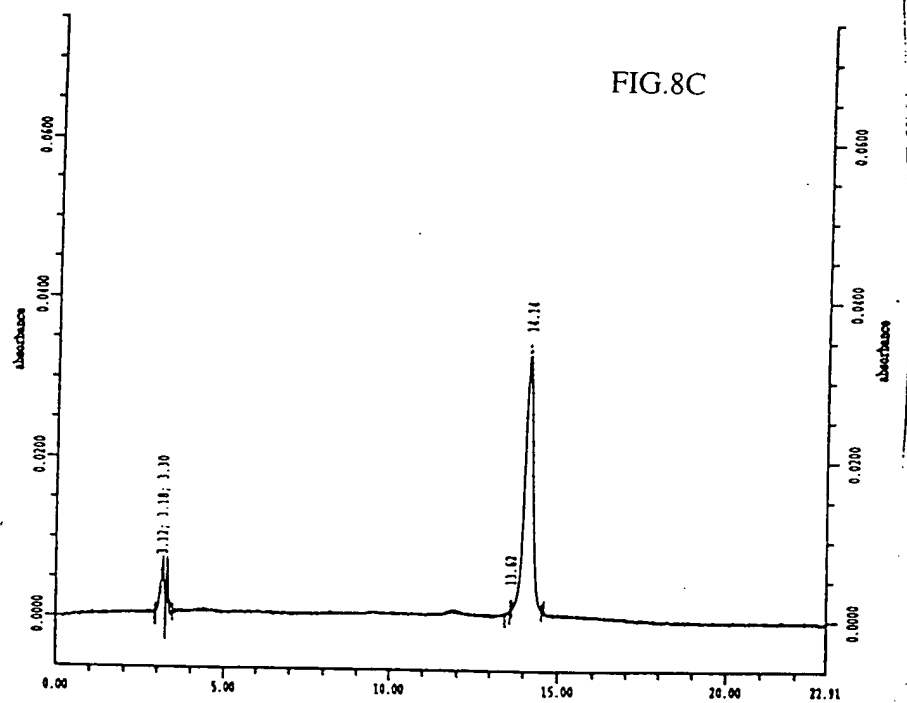


FIG.7

09203078 120198



09203073 420493



09203078.120198

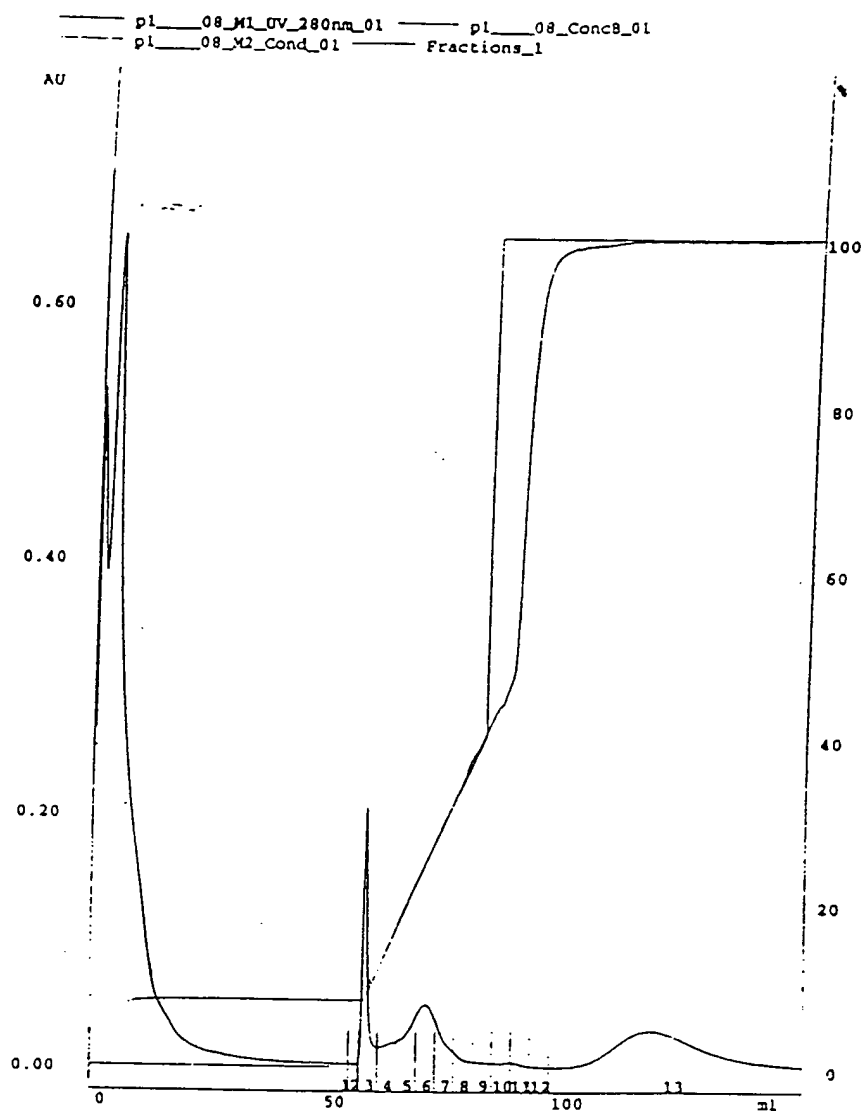
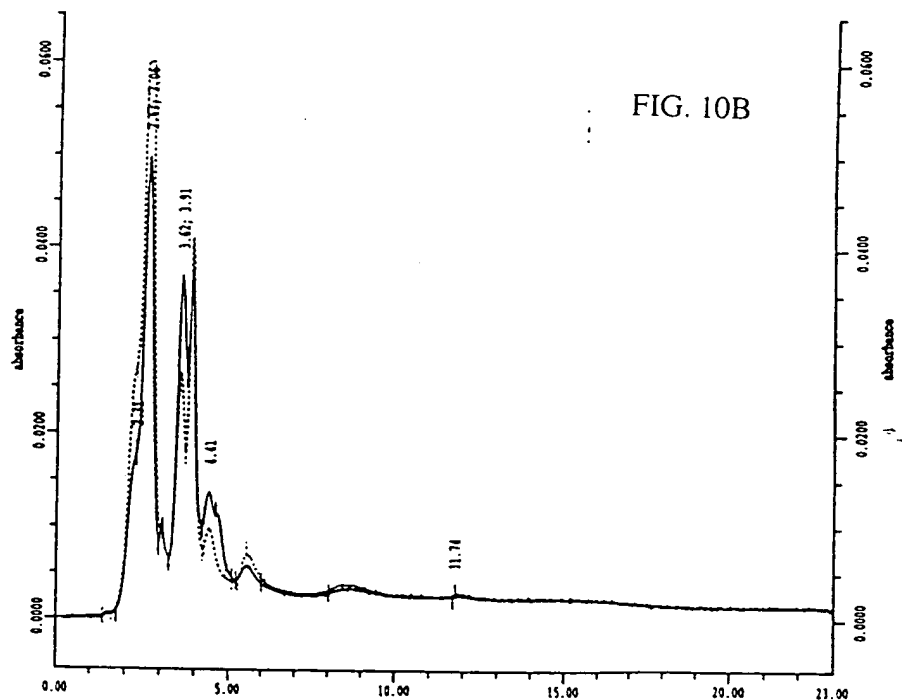
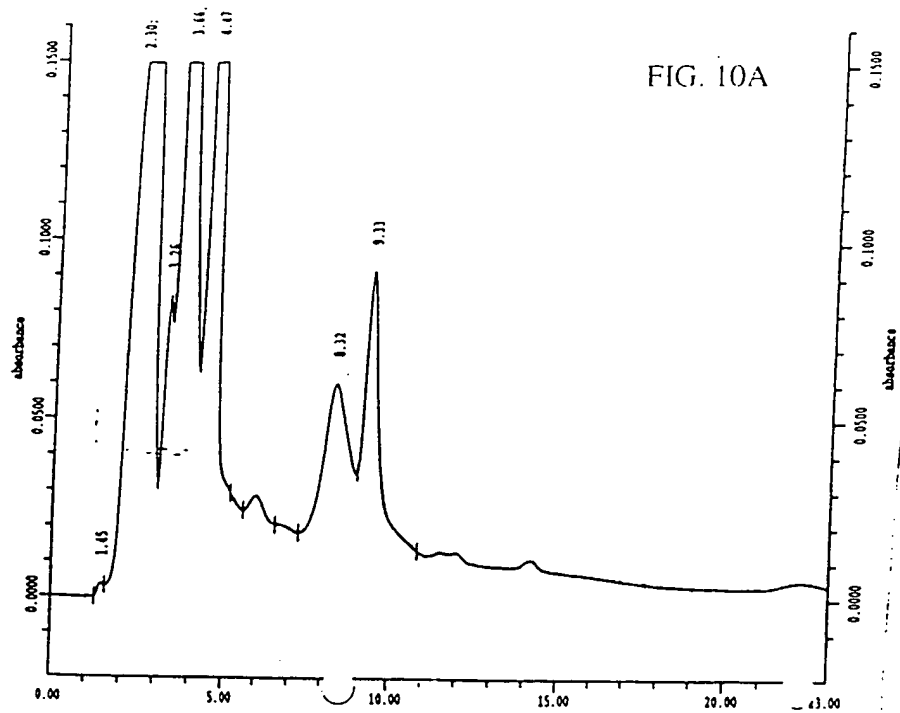
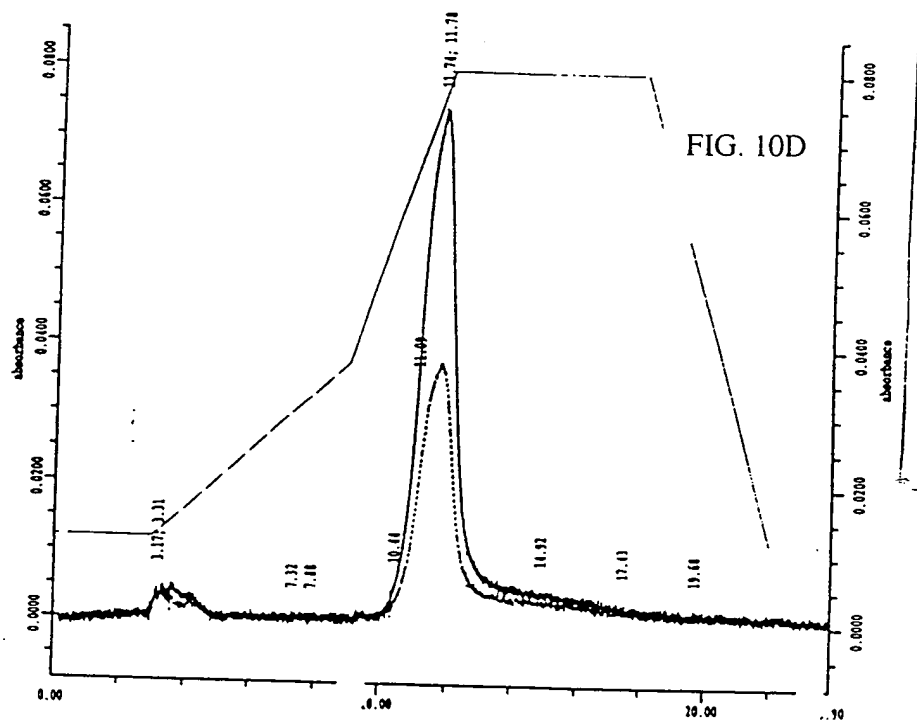
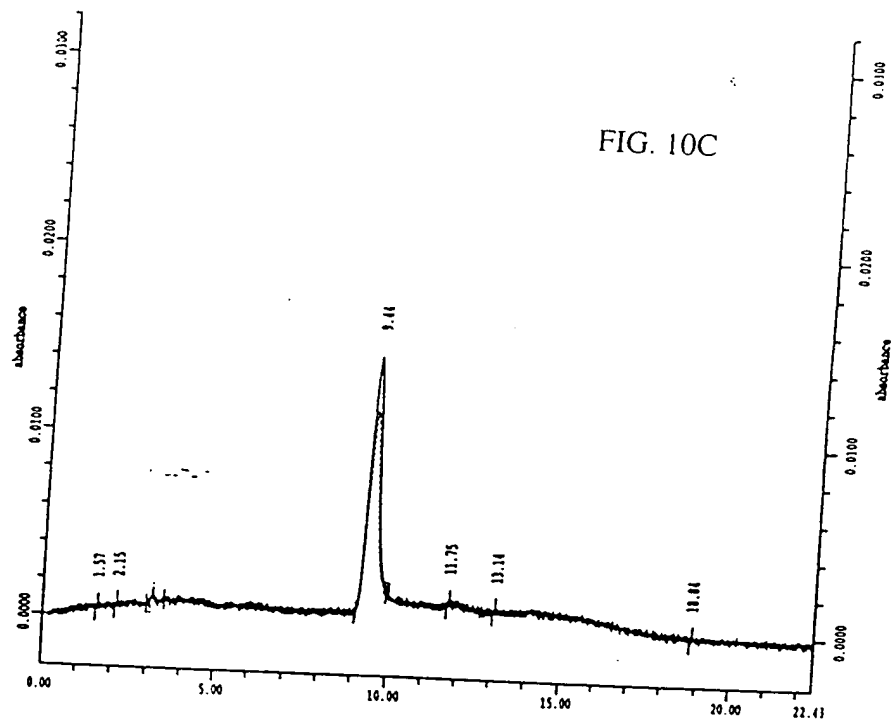


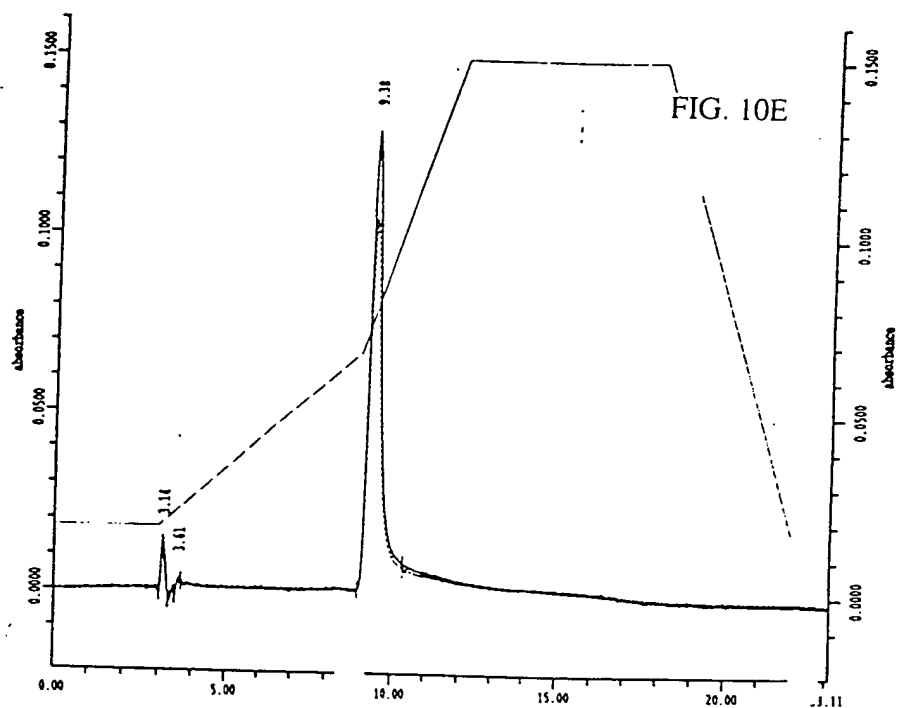
FIG. 9



09203078.420498



09203078 120198



09203078 120198

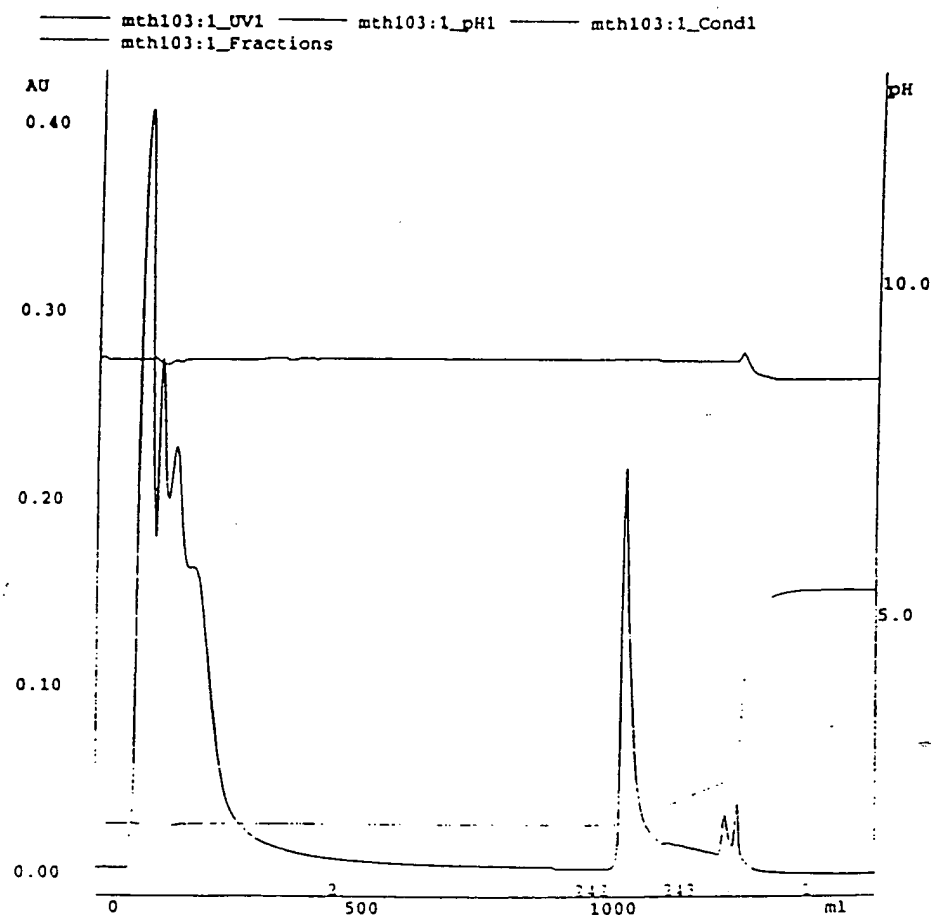


FIG. 11

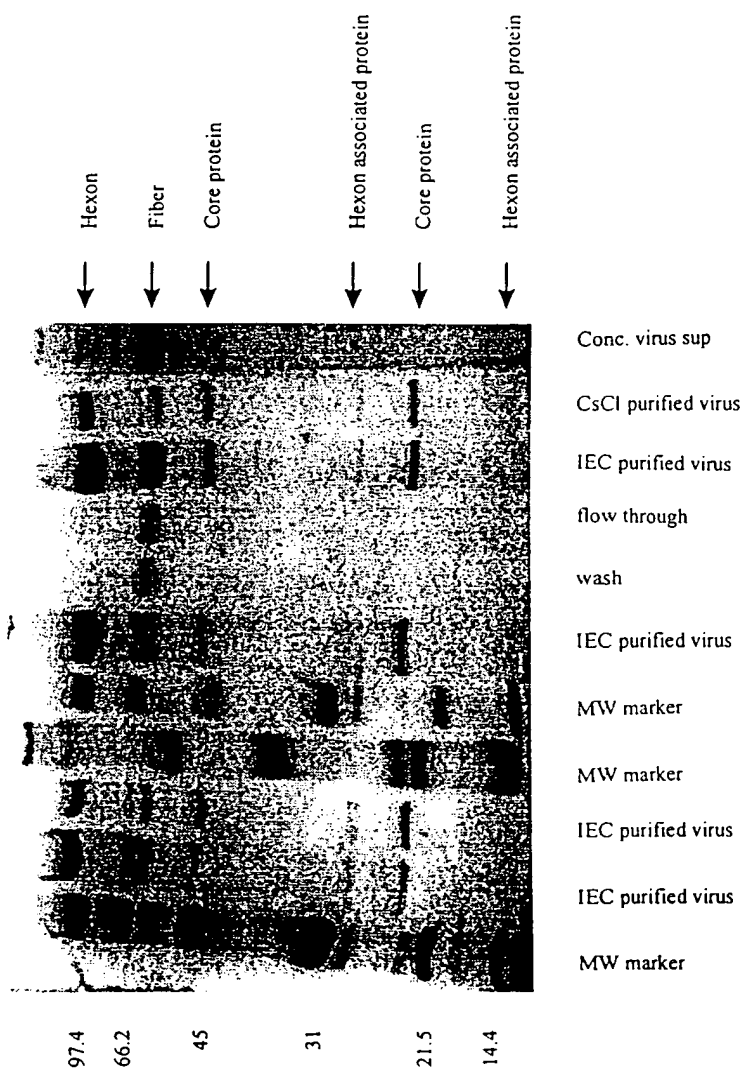


FIG. 12

06T02T" 020E0260

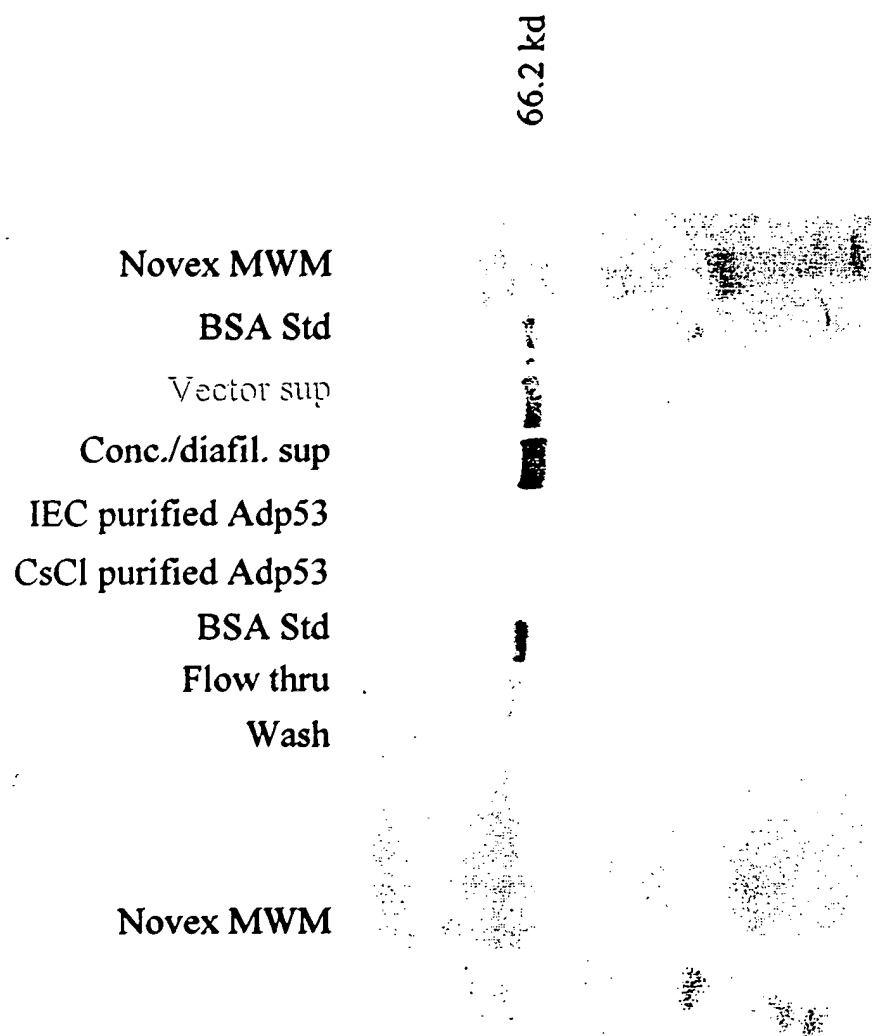


FIG. 13

09203078-120198

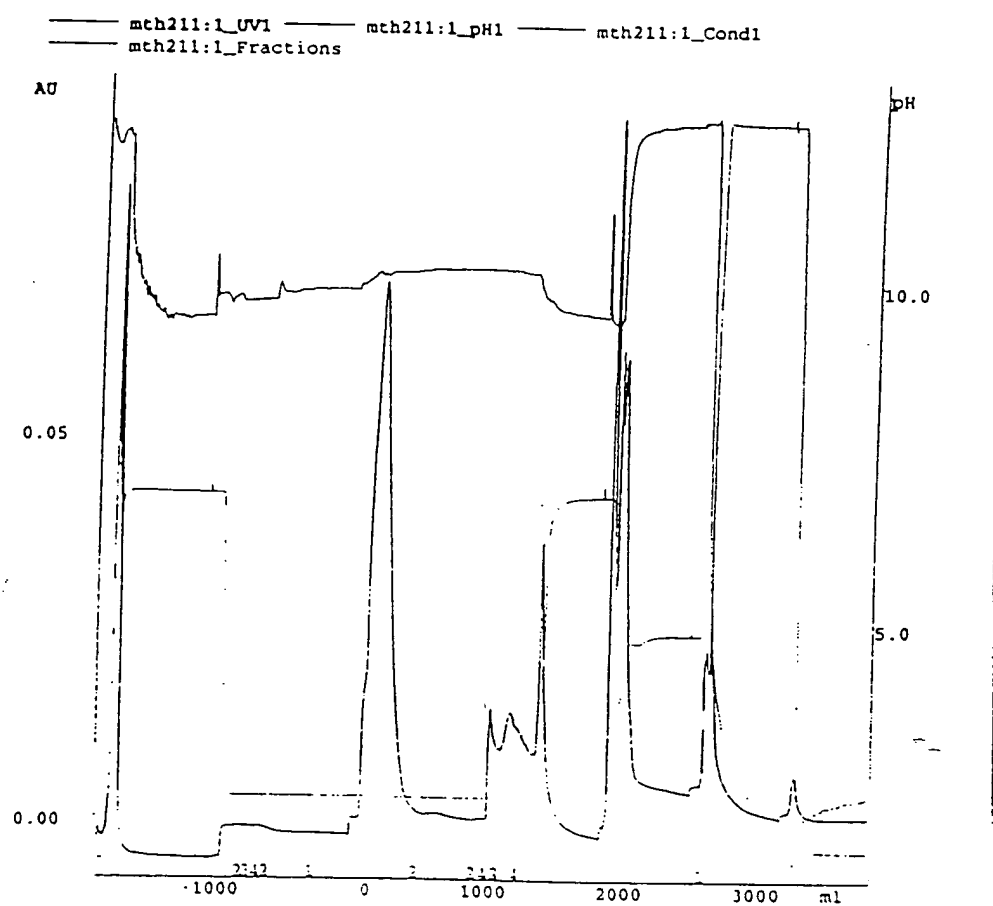


FIG. 14

09203078-120198

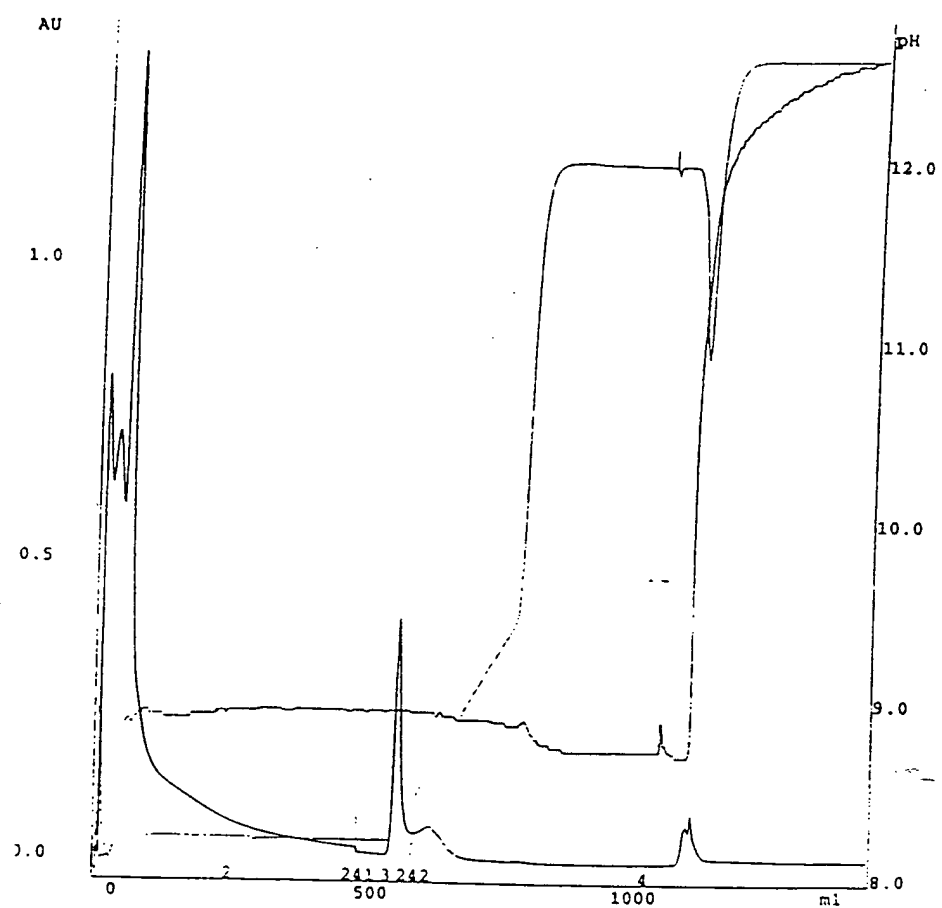
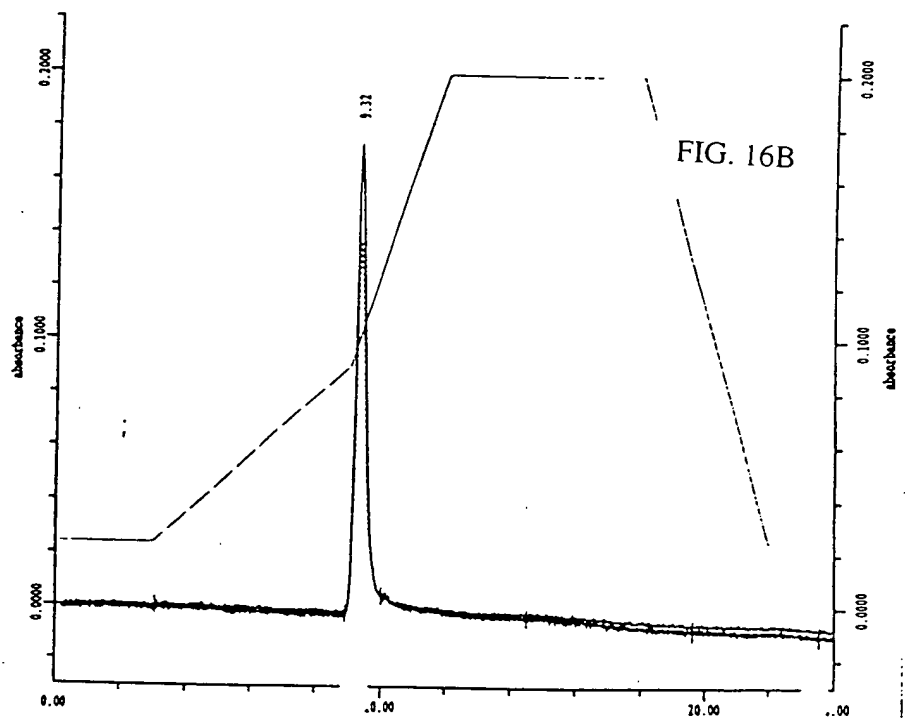
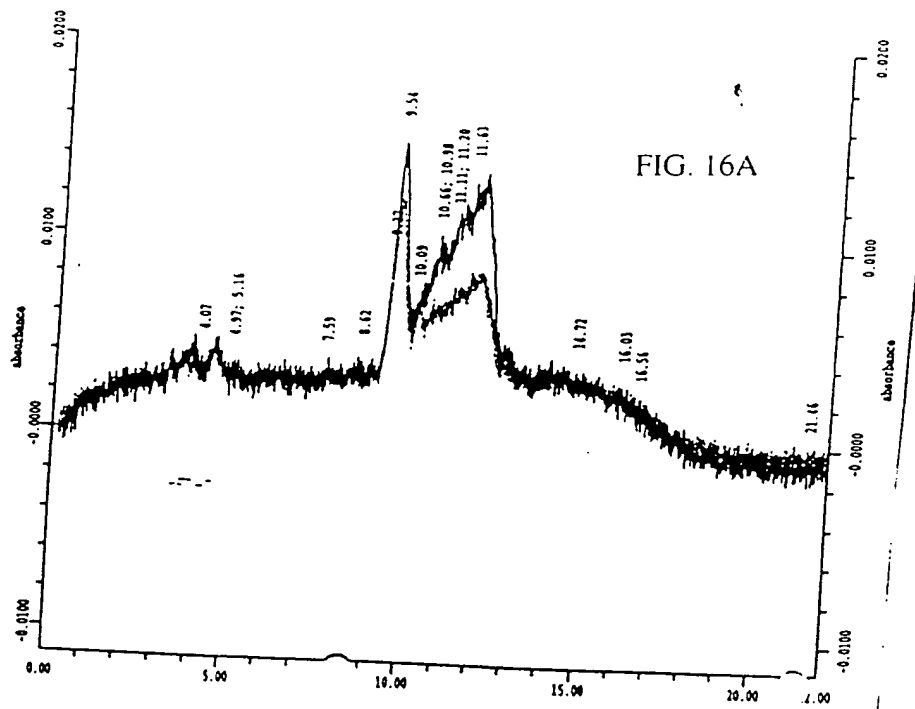


FIG. 15

09203078-120498



09203078.120498

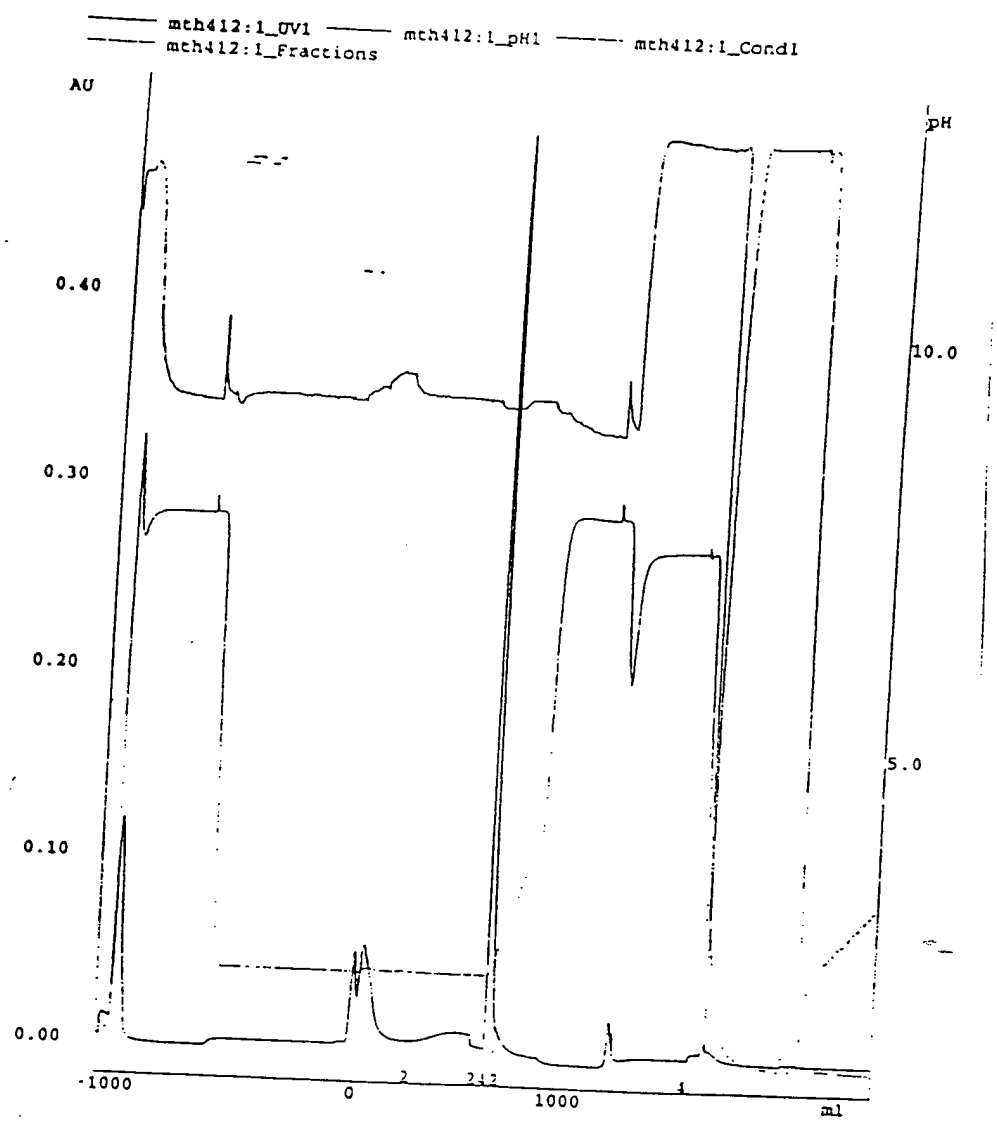


FIG. 17

05T02T" 02000260

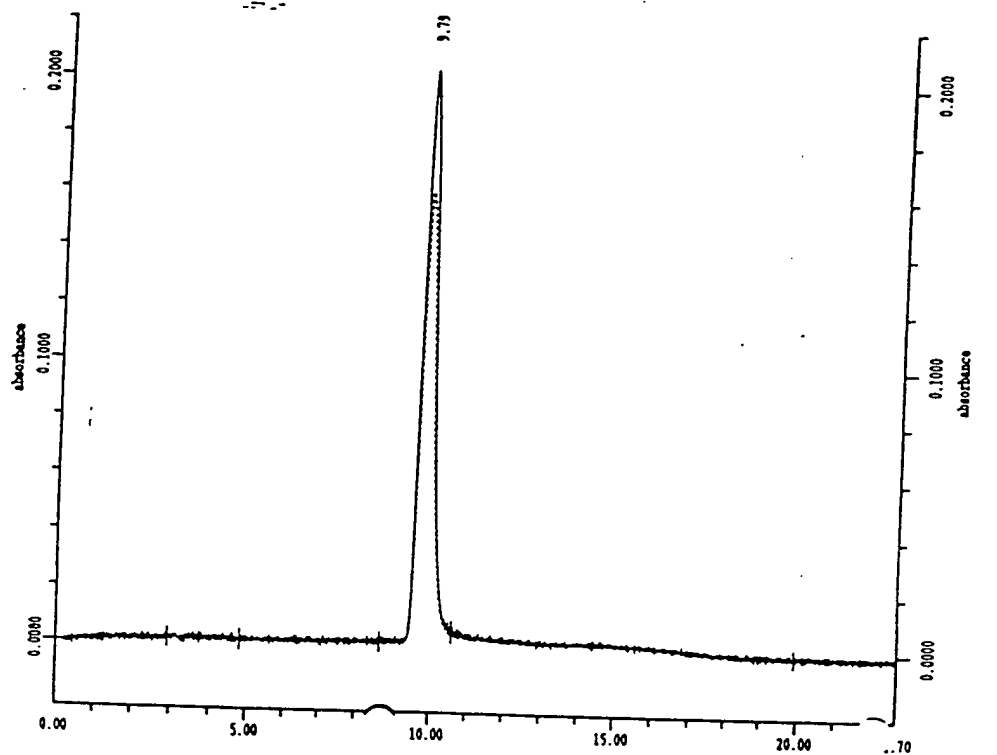


FIG. 18

FIG. 19A



97
66
45
31
21.5
14

Tween-20 harvest
Conc. Tween-20 harvest
Flow thru
IEC purified Adp53
IEC purified Adp53
IEC purified Adp53
Conc. IEC purified Adp53
Conc. IEC purified Adp53
Defective virus
CsCl purified Adp53
MWM

06F02T" 820E0260

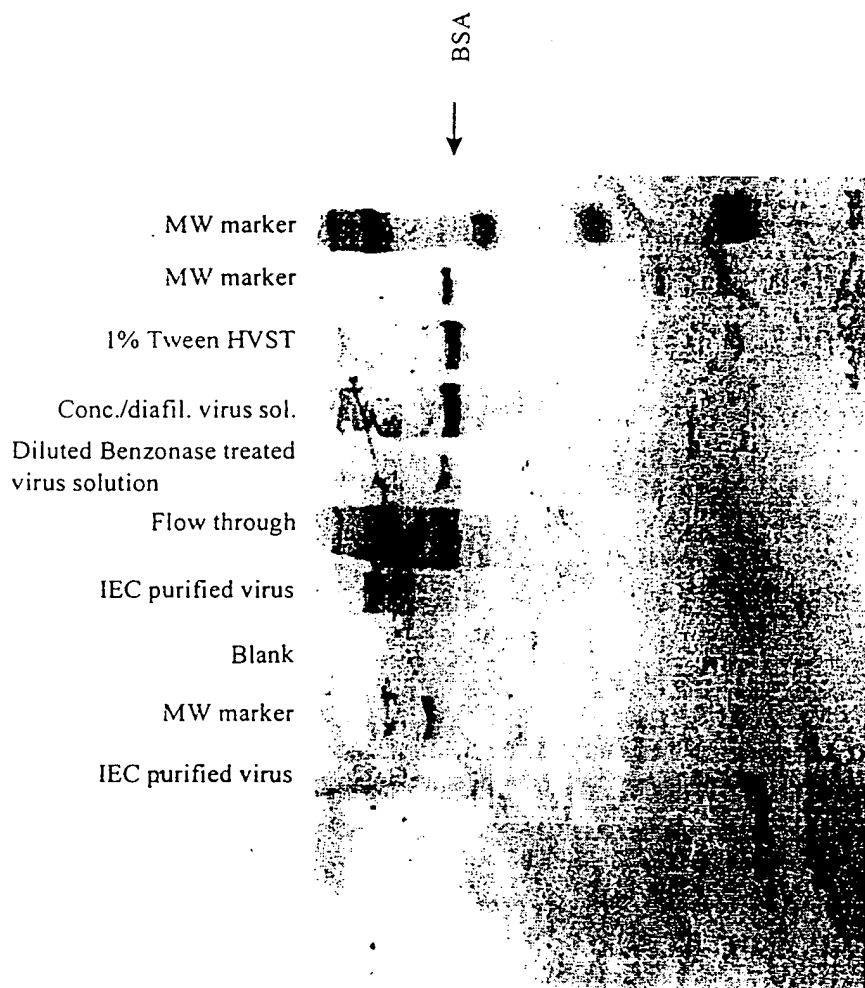


FIG. 19B

86F02F" 840E0260

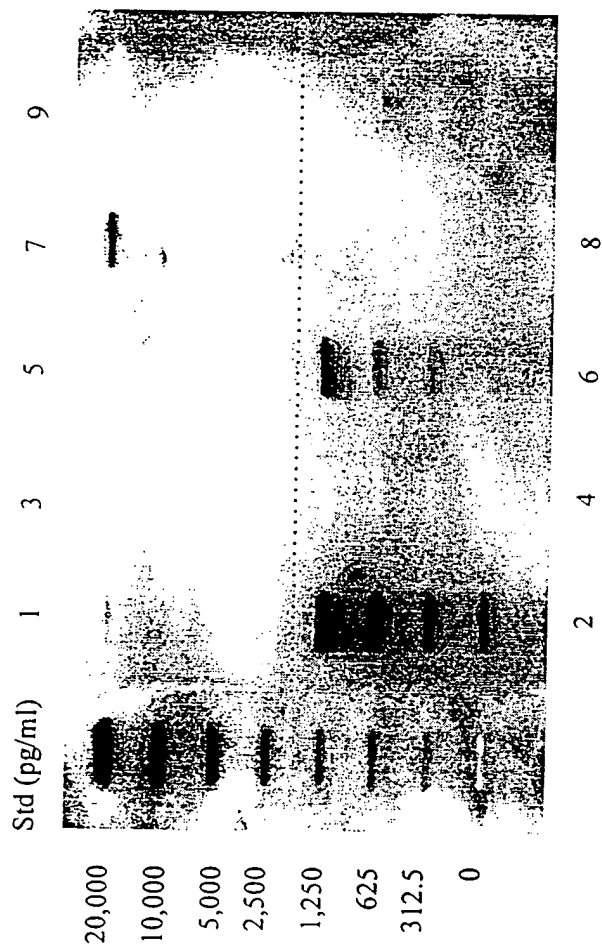
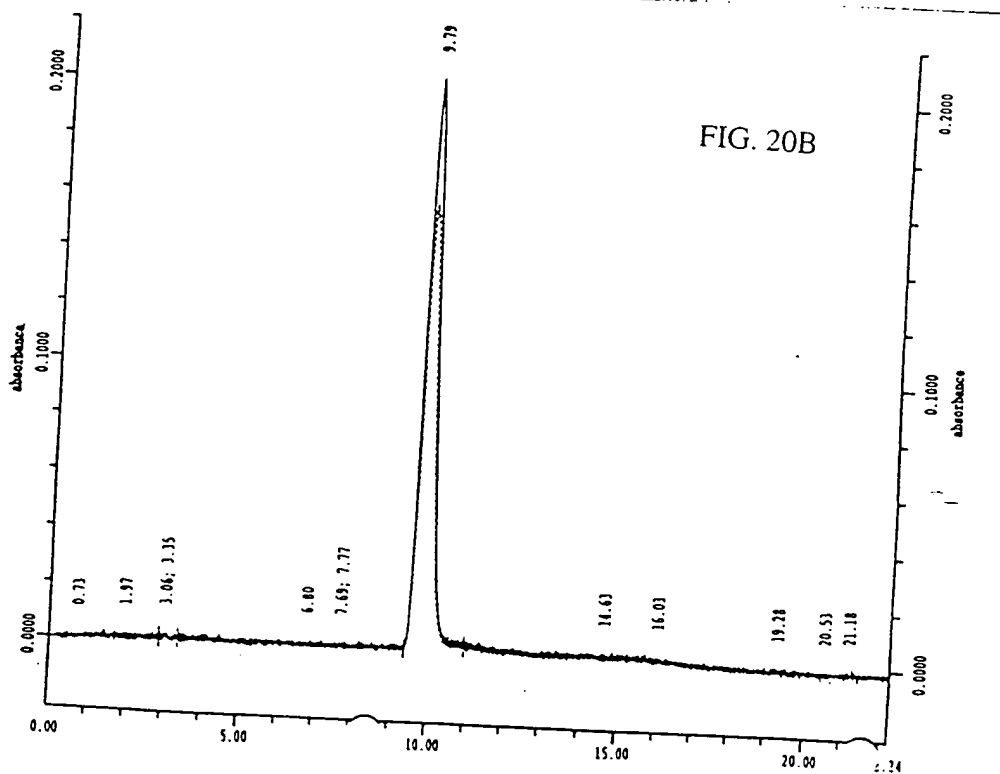
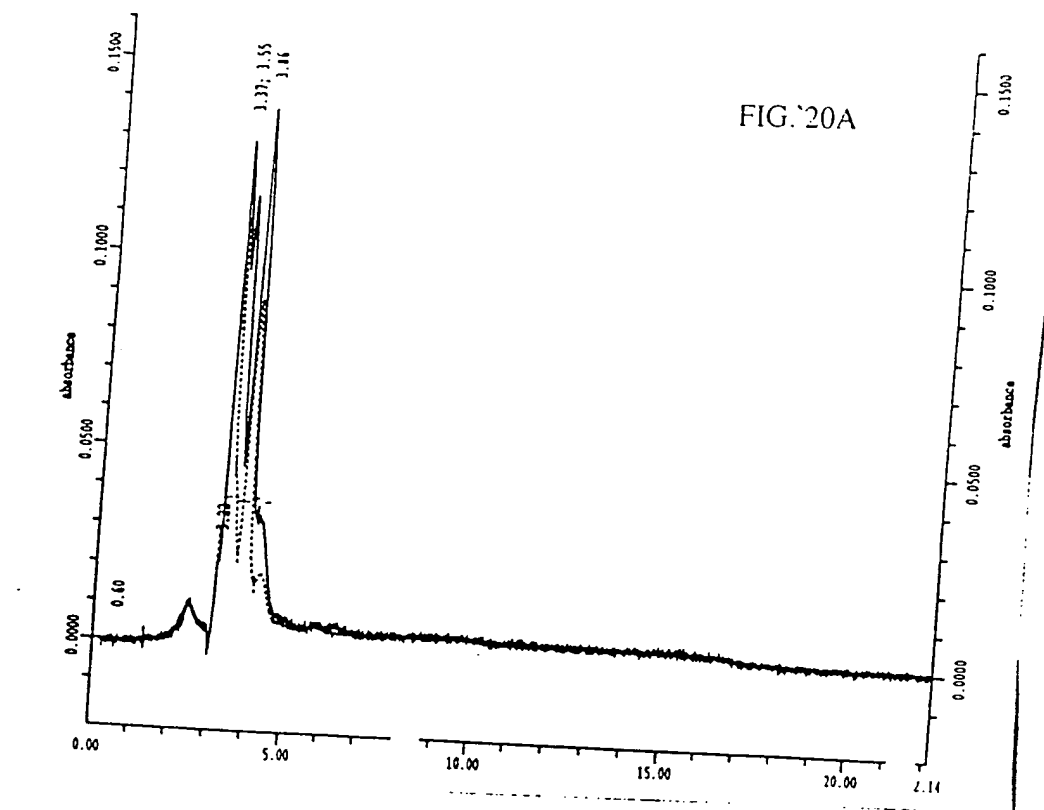
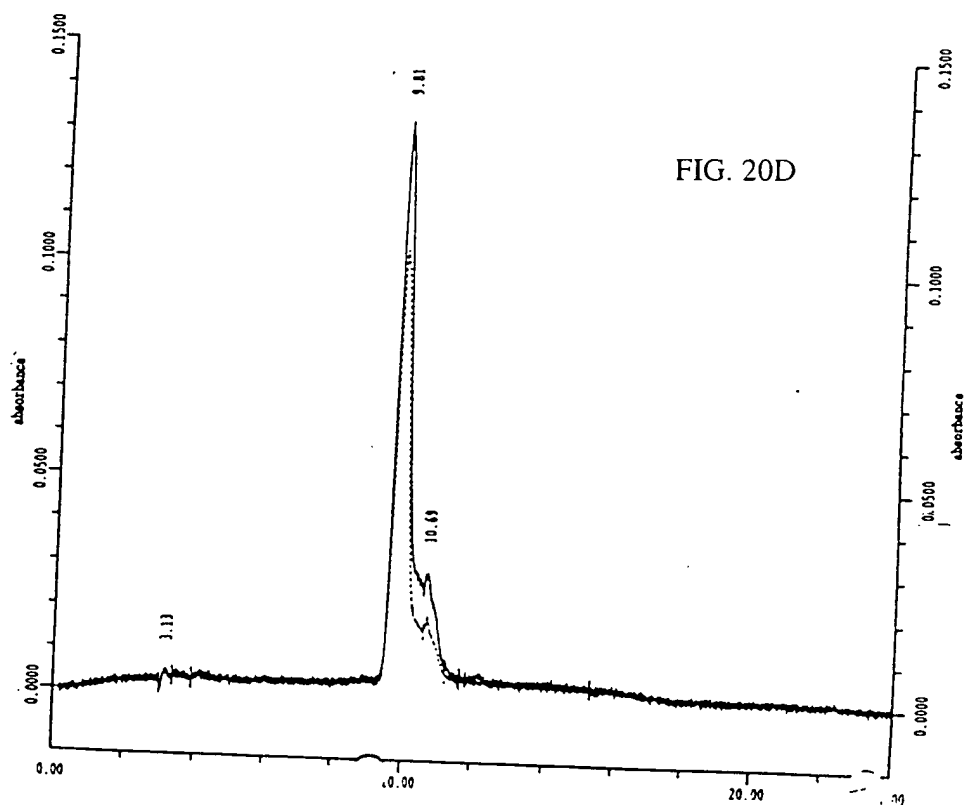
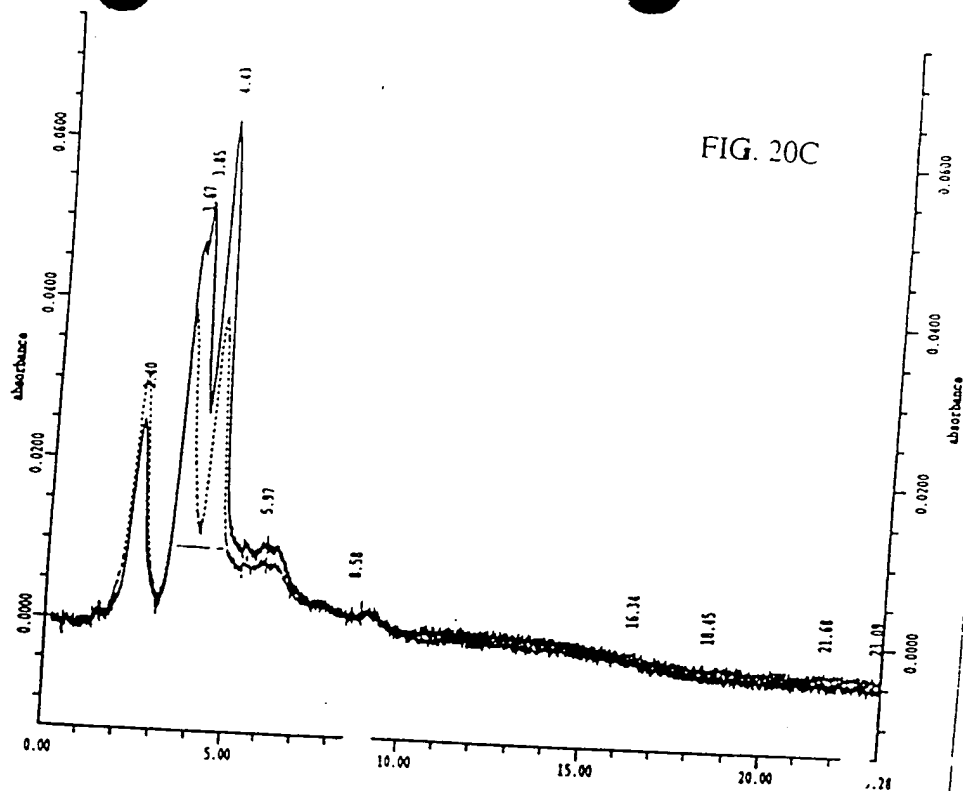
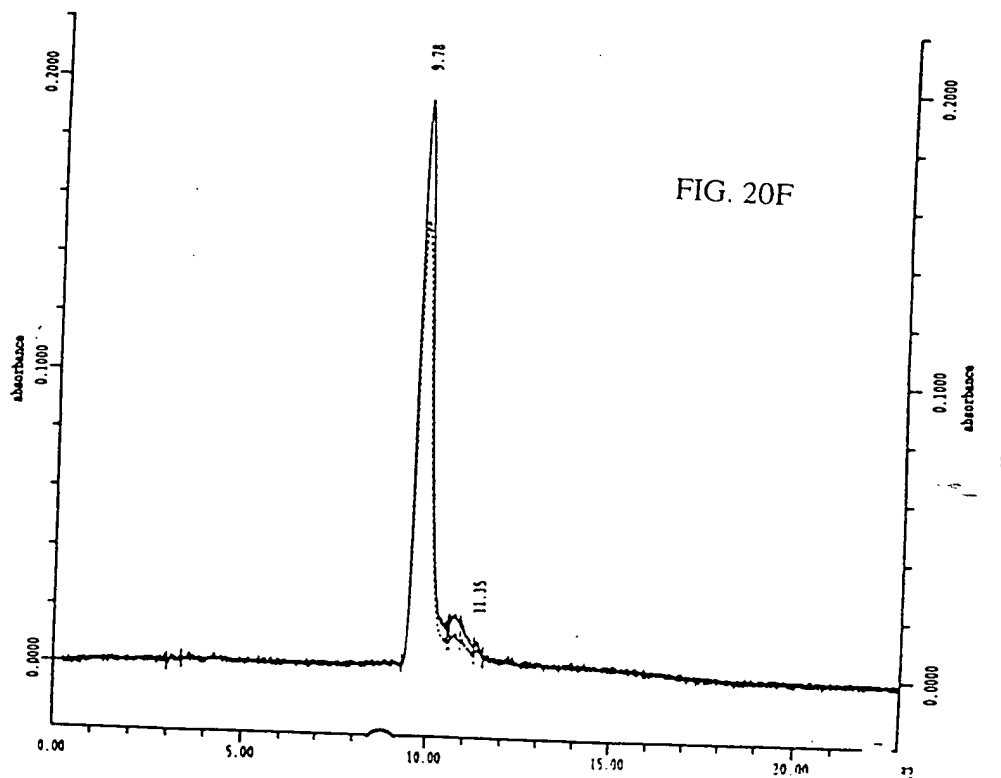
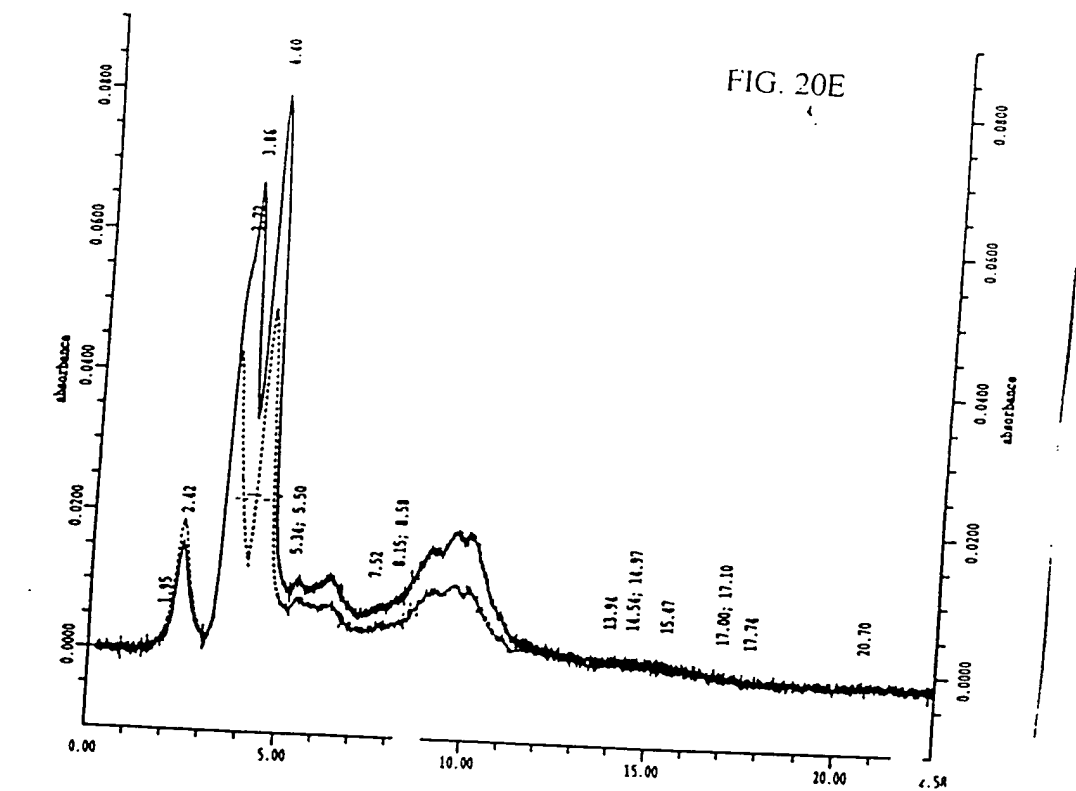


FIG. 19C



09203078-12098





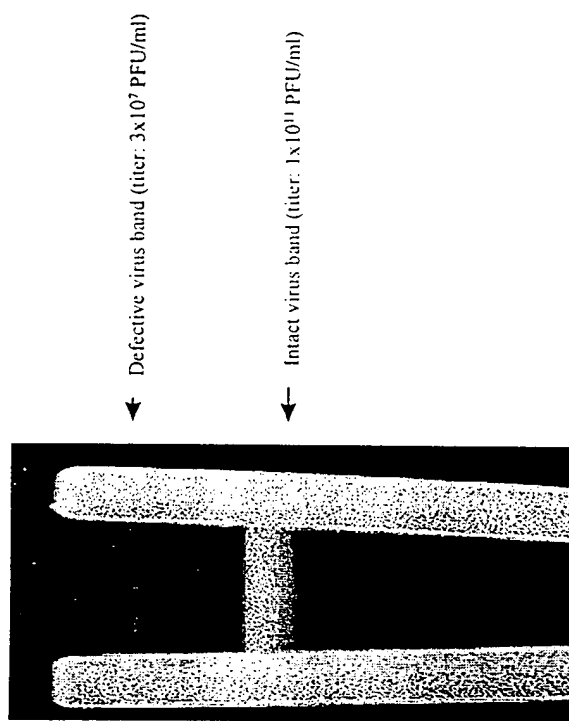
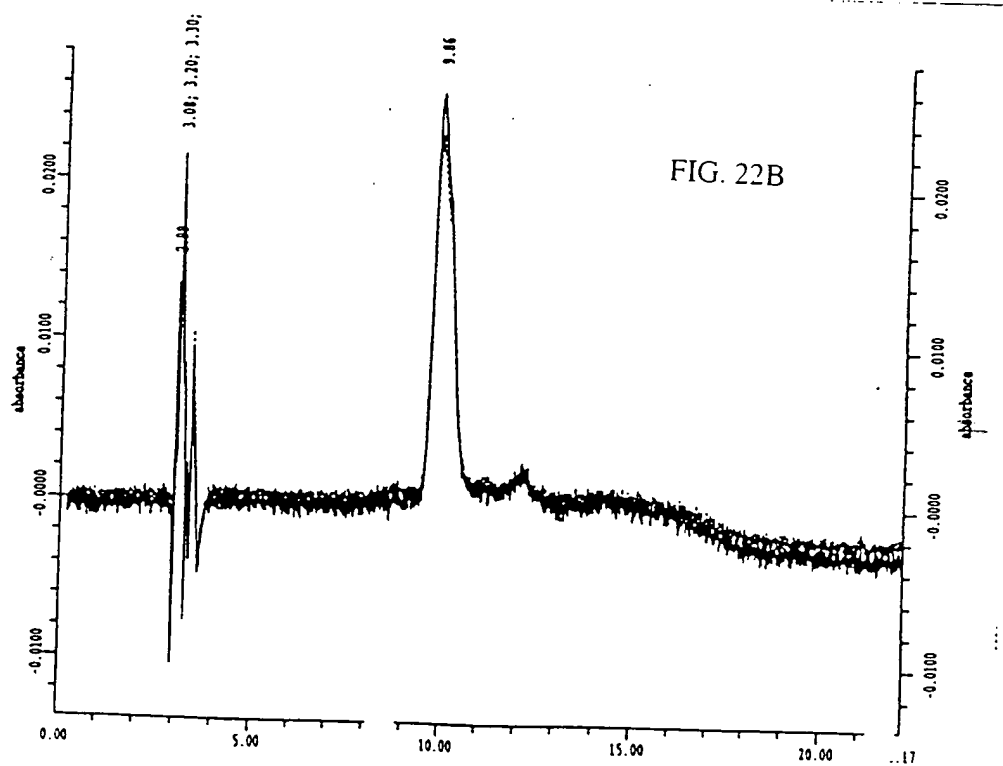


FIG. 21

FIG. 22A



	Titer (PFU/ml)	Vol. (ml)	Yield (PFU)	Recovery (%)	
				Step	Acc.
Cube (low perfusion rate, keep glucose > 1g/L)					
↓ 1% Tween-20 in buffer A					
Harvest					
↓ Clarification and Filtration (0.22 um)					
Virus solution	2.6×10^9	1900	4.9×10^{12}		
↓ Conc./diaf. (10-fold conc., diaf. into 1M NaCl buffer A)					
Conc. sup	2.5×10^{10}	200	5×10^{12}	102%	
↓ Benzonase treatment (O/N, RT, 100u/ml)					
Treated sup					
↓ Dilute with water to conductivity = 22-25 mS/cm					
Diluted virus solution	7×10^9	700	4.9×10^{12}	98%	100%
↓					
Purified virus	1.5×10^{10}	240	3.6×10^{12}	73%	73%
↓ conc./diaf (5-fold conc.)					
Final purified product	7×10^{10}	50	3.5×10^{12}	97%	71%

FIG. 23

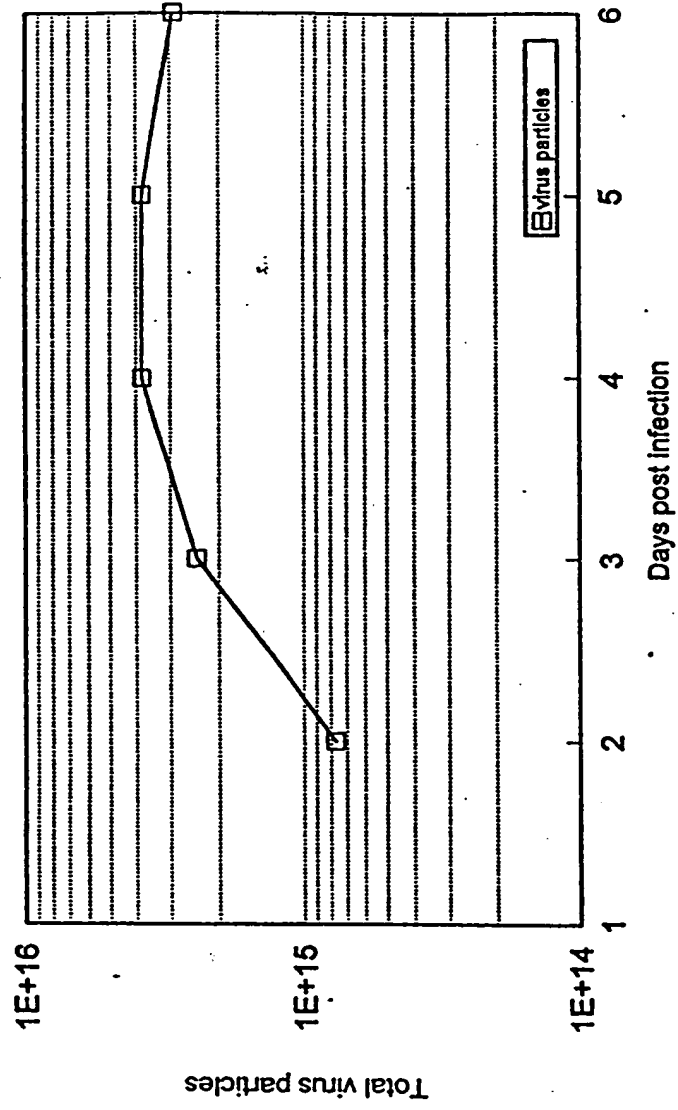


FIG. 24

86F02T" 84050260

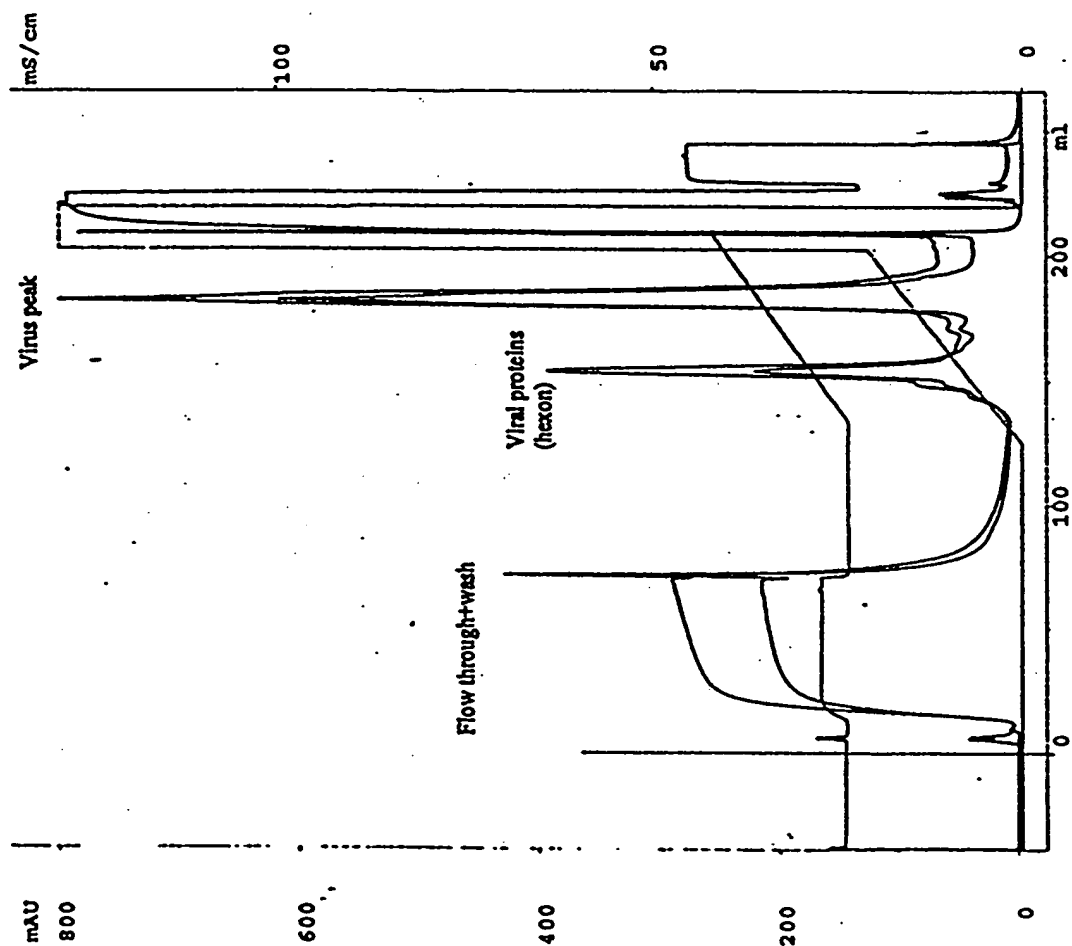


FIG. 25

06T02T 820E0260

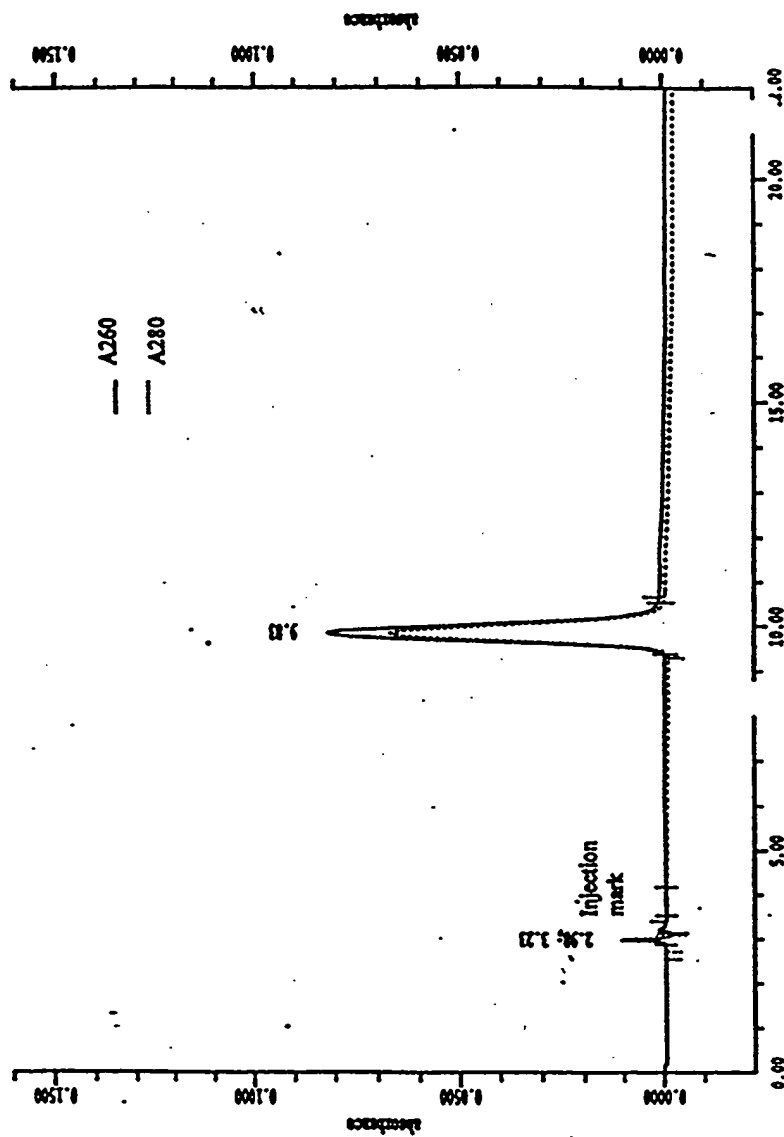


FIG. 26

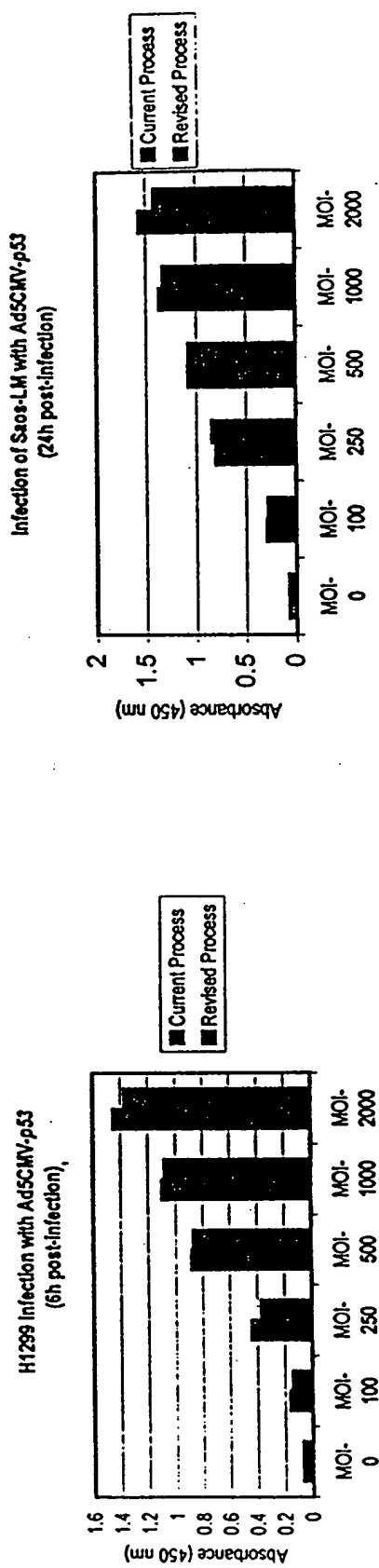


FIG. 27

The Revised Process (to be used in support of Clinical Study T203)

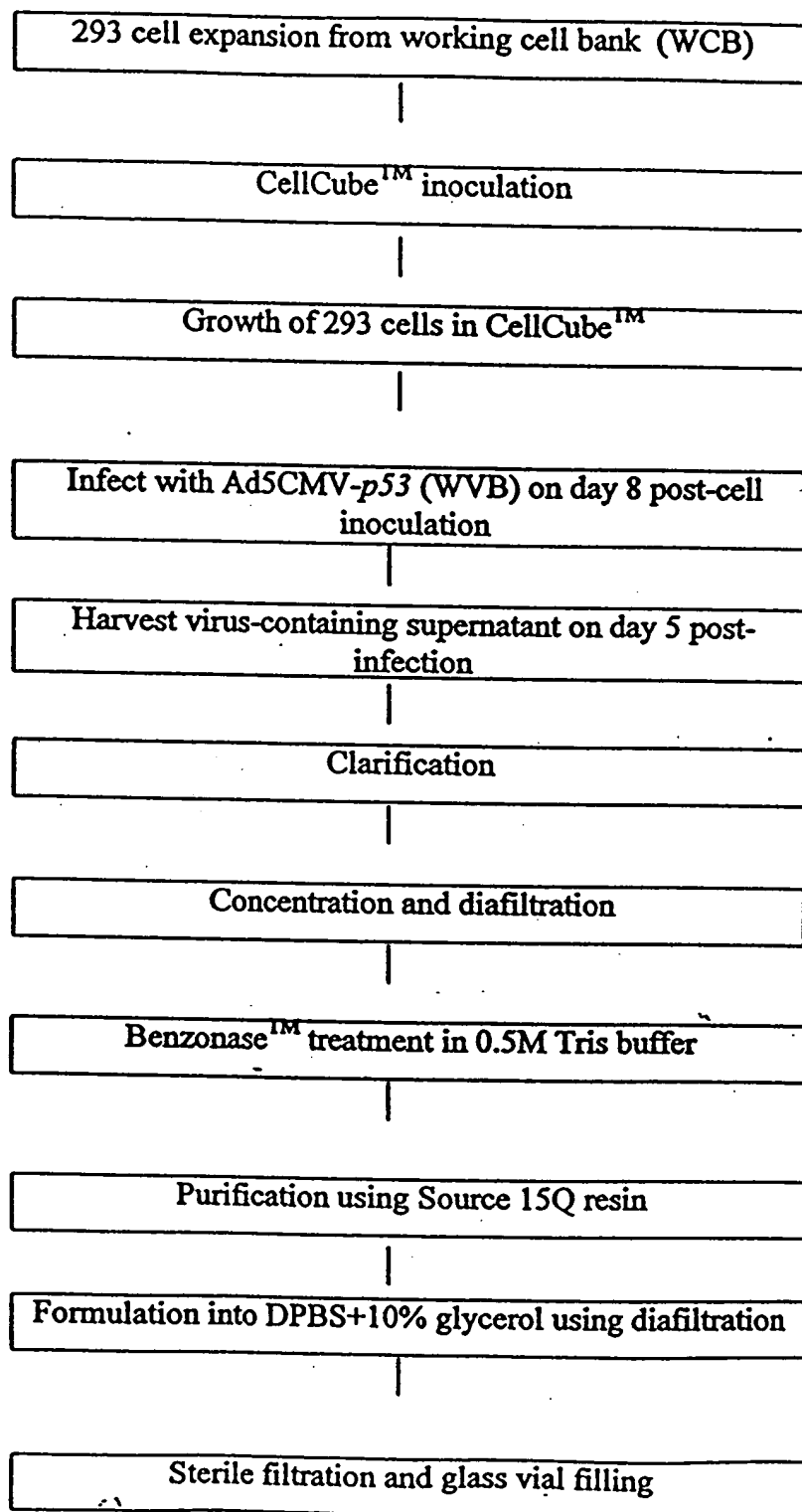
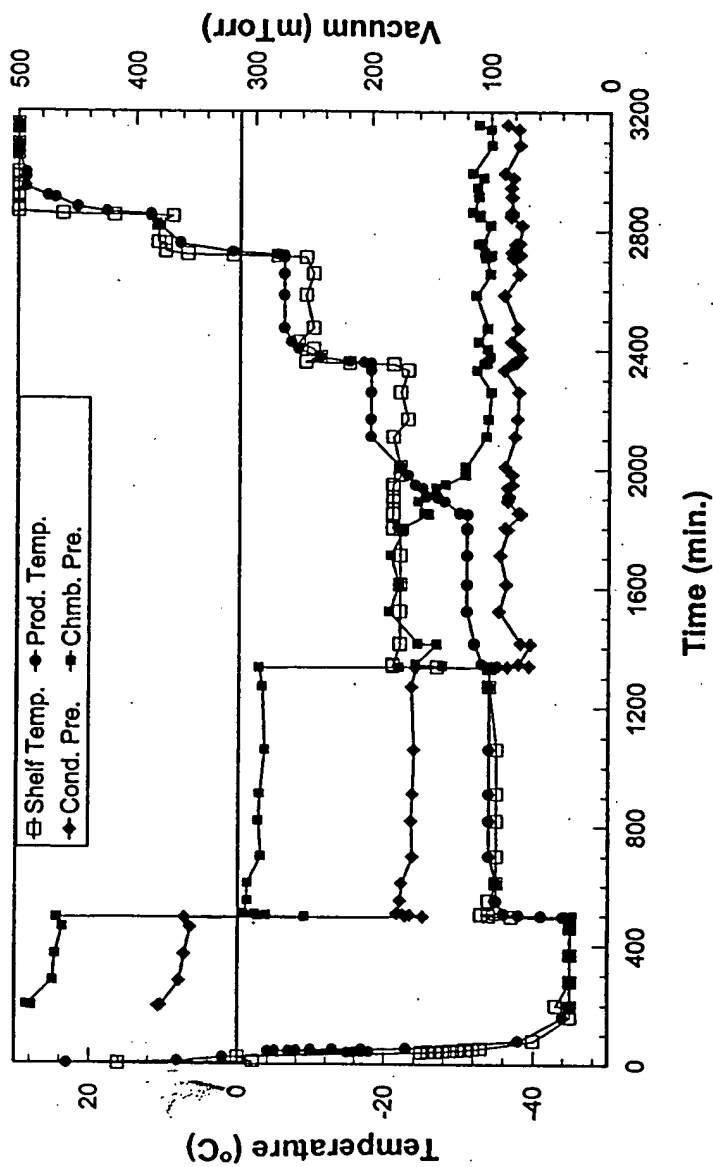


FIG. 28



Lyophilization Cycle

FIG. 29

Secondary drying at 10°C
Formulation set 10 (6-9) + Adp53 (run1)

Date (Temp.)	PFU x10 ⁹ /ml				HPLC viral particles (x10 ¹⁰ /ml)				Water Content (W%)			
	Set10-6	Set 10-7	Set 10-8	Set 10-9	Set10-6	Set 10-7	Set 10-8	Set 10-9	Set 10-6	Set 10-7	Set 10-8	Set 10-9
4/11/97	5.5	6	5.8	6.5	24.5	24.6	24.9	26.7	2.2	2.5	2.7	3.3
5/15/97 (-20°C)	7.6	7.1	7.5	8.1	22.4	25.6	26.8	28.5	2.2	2.5	2.8	3.3
5/15/97 (4 °C)	6.5	6.3	6.5	10	22	23	24	27.5	2.4	2.6	3	3.4
5/15/96 (r.t.)	7.1	7.1	6.7	3.3	14.5	16.5	6.2	4.2	2.7	2.9	3.2	3.5
7/18/97(-20 °C)	6.8	6.4	6.8	7.2	28.7	28.9	28.6	31.2	2.3	2.5	2.8	3.3
7/18/97(4 °C)	6	5.8	7.3	9	25	26.6	27.6	31.1	2.5	2.8	3	3.6
7/18/97(r.t.)	1.2	0.8	4	1.4	0.9	1.8	0.7	0.7	2.7	2.9	3	3.4
10/22/97(-20 °C)	7.9	7.5	7.9	7.8	25.5	25	25.4	26.2	2.4	2.6	2.8	3.1
10/22/97(4 °C)	6.8	6.8	5.8	8	22	23	24.7	24.2	2.7	2.9	3.2	3.6
10/22/97(r.t.)	< 0.01	< 0.01	< 0.01	< 0.01	N.D.	N.D.	N.D.	N.D.	2.7	2.9	3.1	3.4
4/16/98(-20 °C)	6	5.8	7.1	7.2	19.3	20.3	23.5	26.1	2.4	2.6	3	3.4
4/16/98(4 °C)	5.4	7.2	6.1	6.3	21.7	22.8	22.9	24.6	2.9	3.1	3.3	3.8
4/16/98(r.t.)	0.0003	0.001	0.0007	0.001	N.D.	N.D.	N.D.	N.D.	2.7	2.9	3.1	3.4

N.D.: not detectable

CONTROLS

Date	PFU x10 ⁹ /ml				HPLC viral particles (x10 ¹⁰ /ml)			
	Set 10-6	Set 10-7	Set 10-8	Set 10-9	Set 10-6	Set 10-7	Set 10-8	Set 10-9
4/11/97	5.5	7	7	7	35.5	35.8	36	36.9

Run 1: secondary drying at 10 °C
Formulation set 10: 6%-mannitol, 0.5% HSA, 1% glycerol and different percentages of sucrose in 10 mM-tris buffer (pH = 7.5, 1mM MgCl₂)

FIG. 30A

Formulation set 11 (6-9) + Adp53 (run1)

Date (Temp.)	PFU x10 ⁹ /ml			HPLC viral particles (x10 ¹⁰ /ml)			Water content (W%)					
	Set 11-6	Set 11-7	Set 11-8	Set 11-9	Set 11-6	Set 11-7	Set 11-8	Set 11-9	Set 11-6	Set 11-7	Set 11-8	Set 11-9
5/2/97	7	6	6.3	5.8	28.5	28.8	28.4	29.5	2.3	2.7	3.5	4
6/20/97 (-20 °C)	6.2	6.6	6.9	6.5	26.3	25	27	27.3	2.2	2.8	3.4	4.6
6/20/97 (4 °C)	6.1	6	6.5	6.5	24.1	22.1	25.6	26.6	2.5	2.8	3.5	4.8
6/20/97(R.T.)	3.3	3	1	<0.1	20.5	17.4	5.2	9.1	2.7	3.1	3.5	4.7
8/18/97(-20 °C)	8	7.2	7.5	7.6	21.6	21.8	25.3	24.9	2.3	2.8	3.7	4.9
8/18/97(4 °C)	8	7.3	8	8	22.7	22.7	24.9	25	2.6	3	3.9	4.2
8/18/97(R.T.)	<0.1	<0.1	<0.1	<0.1	N.D.	N.D.	0.2	13.1	2.7	3	3.5	4.4
10/22/97(-20 °C)	7.9	7.5	7.9	6.7	21	22	25.1	24	2.4	3	3.9	4.4
10/22/97(4 °C)	6	6.9	6.8	7.3	21.4	22	23.1	23.1	2.6	3	3.3	4.6
10/22/97(R.T.)	<0.01	<0.01	<0.01	0.015	N.D.	N.D.	N.D.	9	2.7	2.9	3.9	5
5/8/98(-20 °C)	8.3	7.5	8	8.7	19	18.2	19.9	21.1	2.6	3.1	4	4.6
5/8/98(4 °C)	7	7.1	7.8	6.5	17.3	17.1	18.2	17.8	2.8	3.2	4.1	5.1
5/8/97(R.T.)	0.00033	0.000065	0.00045	0.000016	N.D.	N.D.	N.D.	N.D.	2.7	2.9	4	4.9

N.D.: not detectable

CONTROLS

Date	PFU x10 ⁹ /ml			HPLC viral particles (x10 ¹⁰ /ml)		
	Set 11-6	Set 11-7	Set 11-8	Set 11-9	Set 11-6	Set 11-7
5/2/97	6.4	6.8	6.5	6.5	37.7	36.7
					37.3	36

Run 1: secondary drying at 10 °C

Formulation set 11: 5%-mannitol, 0.5% HSA, 1%-glycerol and different percentages of sucrose in 10 mM-tris buffer (pH = 7.5, 1mM MgCl₂)

FIG. 30B

Secondary drying at 30°C without N₂ blanketing

Formulation set 10 (6-9) + Adp53 (run2)

Date (Temp.)	PFU x10 ⁹ /ml				HPLC viral particles (x10 ¹⁰ /ml)				Water content (W%)			
	Set 10-6	Set 10-7	Set 10-8	Set 10-9	Set 10-6	Set 10-7	Set 10-8	Set 10-9	Set 10-6	Set 10-7	Set 10-8	Set 10-9
5/15/97	6.5	5.6	6.1	6	18	18.6	21.9	23.3	0.8	1.1	1.3	1.5
6/20/97(4 °C)	5.4	5.6	5.5	5.5	14.6	14.9	17.2	16.6	0.8	1.2	1.5	1.6
6/20/97(R.T.)	4.5	5	5.5	6	10.8	11.8	15	15.4	1.3	1.4	1.6	1.9
8/18/97(4 °C)	7	6.7	6.8	7	15.3	17.1	17.9	17.7	1.3	1.5	1.5	1.7
8/18/97(R.T.)	2.4	2.2	4.8	5.8	4.3	7.2	11.7	14.2	1.3	1.6	1.7	2.1
11/20/97(4 °C)	5.5	5.5	5.3	5.7	16.8	16.8	20.6	20.1	1.1	1.4	1.6	1.9
11/20/97(R.T.)	0.45	0.9	2.3	3.1	1.5	5.5	7.3	10.7	1.3	1.7	1.8	2.2
5/14/98(4 °C)	4.9	4.7	5.4	6.5	9.7	11.9	12.6	14.2	1.2	1.6	2.2	1.4
5/14/98(R.T.)	0.000006	0.00006	0.00004	0.000024	N.D.	N.D.	N.D.	N.D.	1.4	1.6	1.3	2

N.D.: not detectable

CONTROL

Date	PFU x10 ⁹ /ml				HPLC viral particles (x10 ¹⁰ /ml)			
	Set 10-6	Set 10-7	Set 10-8	Set 10-9	Set 10-6	Set 10-7	Set 10-8	Set 10-9
5/15/97	7	5.6	7	7	31.2	30.6	31.6	31.4

Run 2: secondary drying at 30 °C

Formulation set 10: 6%-mannitol, 0.5% HSA, 1%-glycerol and different percentages of sucrose in 10 mM-tris buffer (pH = 7.5, 1mM MgCl₂)

FIG. 31A

Formulation set 11 (6-9) + Adp53 (run2)

Date (Temp.)	PFU x10 ⁹ /ml			HPLC viral particles (x10 ¹⁰ /ml)			Water content (W%)		
	Set 11-6	Set 11-7	Set 11-8	Set 11-9	Set 11-6	Set 11-7	Set 11-8	Set 11-9	Set 11-9
5/22/97	7.5	6.3	7.3	6.5	17.4	16.6	20.3	24.7	1
6/20/97 (4 °C)	5.5	6.3	6	7.5	14.8	16.1	17.5	21.1	1.2
6/20/97 (R.T.)	5	6	6	7.5	12.6	14.9	17.2	20.3	1.4
8/18/97(4 °C)	6.3	6.7	6.8	7.5	15.7	17.2	18.5	22.6	1.2
8/18/97(R.T.)	3.3	4.5	5.5	7	7.4	10.5	15.8	21.2	1.6
11/20/97(4 °C)	5.3	5.6	5.3	6.6	17.3	20	22.6	26.3	1.2
11/20/97(R.T.)	0.8	1.9	3	0.2	3.2	7.9	14.2	1.3	1.6
5/14/98(4 °C)	6.7	7.2	6.9	7.6	12.4	13.9	15.5	18.5	1.3
5/14/98(R.T.)	0.0013	0.00005	0.00031	0.00045	N.D.	N.D.	N.D.	N.D.	1.6

N.D.: not detectable

CONTROL

Date	PFU x10 ⁹ /ml			HPLC viral particles (x10 ¹⁰ /ml)		
	Set 11-6	Set 11-7	Set 11-8	Set 11-9	Set 11-6	Set 11-7
5/22/97	8	7.4	8.3	7.6	26.7	27.6

Run 2: secondary drying at 30 °C

Formulation set 11: 5%-mannitol, 0.5% HSA, 1%-glycerol and different percentages of sucrose in 10 mM-tris buffer (pH = 7.5, 1mM MgCl₂)

FIG. 31 B

Secondary drying at 30°C with N₂ blanketing
Formulation set 10 (6-9) + Adp53 (run3)

Date (Temp.)	PFU x10 ⁹ /ml				HPLC viral particles (x10 ¹⁰ /ml)				Water content (W%)			
	Set 10-6	Set 10-7	Set 10-8	Set 10-9	Set 10-6	Set 10-7	Set 10-8	Set 10-9	Set 10-6	Set 10-7	Set 10-8	Set 10-9
6/13/97	3.4	4.3	4.1	4.2	16	16.5	16.1	18.1	0.8	1.1	1.3	1.4
7/18/97 (4 °C)	6.3	6.3	6	6	17.9	19.5	19.9	20.6	0.9	1.2	1.4	1.6
7/18/97 (R.T.)	4.1	5.5	5	5.5	11.4	15.5	18.2	20.6	1.2	1.4	1.7	1.8
9/16/97 (4 °C)	4.2	5.5	4.5	5.1	15.3	16.1	16.4	17.8	1	1.3	1.5	1.7
9/16/97 (R.T.)	0.7	1.2	5	4	2.9	5	9.5	13	1.3	1.5	1.8	2
12/4/97 (4 °C)	5.5	5.3	5.4	5.9	16.1	16.2	18.1	18.5	1.1	1.4	1.6	1.7
12/4/97 (R.T.)	0.3	0.5	2.5	3.4	N.D.	1.7	4.7	8.8	1.4	1.6	1.8	2
6/29/98/(4 °C)	3.8	5.1	5.3	5.4	10.6	10.8	12	12.9	1.3	1.5	1.8	1.9
6/29/98(R.T.)	0.00003	0.00006	0.0001	0.0001	N.D.	N.D.	N.D.	N.D.	1.4	1.6	1.7	1.8

N.D.: not detectable

CONTROL

Date	PFU x10 ⁹ /ml				HPLC viral particles (x10 ¹⁰ /ml)			
	Set 10-6	Set 10-7	Set 10-8	Set 10-9	Set 10-6	Set 10-7	Set 10-8	Set 10-9
6/13/97	4.7	3.8	5.5	6.2	26	26.2	27.4	27.5

Run 3: secondary drying at 30 °C with N₂ gas back-fill

Formulation set 10: 6%-mannitol, 0.5% HSA, 1%-glycerol and different percentages of sucrose in 10 mM-tris buffer (pH = 7.5, 1mM MgCl₂)

FIG. 32A

Formulation set 11 (6-9) + Adp53 (run3)

Date (Temp.)	PFU x10 ⁹ /ml			HPLC viral particles (x10 ¹⁰ /ml)			Water content (W%)		
	Set 11-6	Set 11-7	Set 11-8	Set 11-9	Set 11-6	Set 11-7	Set 11-8	Set 11-9	Set 11-6
6/13/97	3.4	4.2	3.6	4.4	16.1	16.3	18.4	19.3	0.9
7/18/97 (4 °C)	5.5	6.2	6.5	6.2	18	19.5	23	23.9	1
7/18/97 (R.T.)	3.7	6	6.7	7.3	13.7	18.7	21.8	22.8	1.3
9/16/97 (4 °C)	3.9	4	4.6	6	15.6	17.3	19.5	20.6	1.3
9/16/97 (R.T.)	0.8	2.2	4	5.3	3.6	6.8	13.8	14.6	1.5
12/4/97(4 °C)	4.6	5.3	8	6.1	15.7	18.2	21.4	21.6	1.2
12/4/97 (R.T.)	0.4	0.6	0.3	<0.01	N.D.	N.D.	1.7	N.D.	1.6
6/29/98(4 °C)	4.9	5	5.4	6.4	11.4	14.2	13.7	16	1.5
6/29/98(R.T.)	0.0001	0.00015	0.00085	0.0012	N.D.	N.D.	N.D.	N.D.	1.6

N.D.: not detectable

CONTROL

Date	PFU x10 ⁹ /ml			HPLC viral particles (x10 ¹⁰ /ml)		
	Set 11-6	Set 11-7	Set 11-8	Set 11-9	Set 11-6	Set 11-9
6/13/97	4.5	5	4	5	26.5	27.1

Run 3: secondary drying at 30 °C with N₂ gas back-fill

Formulation set 11: 5%-mannitol, 0.5% HSA, 1%-glycerol and different percentages of sucrose in 10 mM-tris buffer (pH = 7.5, 1mM MgCl₂)

FIG. 32B

AQUEOUS FORMULATION SET 1

Date (Storage Conds.)	PFU x10 ⁹ /ml				HPLC viral particles (x 10 ¹⁰ /ml)			
	10%-G	5%-S,5%-HSA	5%-S,-%-PEG	5%-T,1%-PEG	10%-G	5%-S,5%-HSA	5%-S,1%-PEG	5%-T,1%-PEG
8/1/97	5.8	4.7	4.3	4.4	16.9	14.5	16.1	16.7
8/28/97(4°C, N ₂)	5.8	5.8	6.4	6.3	13.3	14.9	13.8	13.4
8/28/97(4°C, Air)	5	5.9	6	5.9	12.9	14.2	12.9	12.9
8/28/97(R.T., N ₂)	4.4	4.8	5	6	12.6	14.5	13.5	12.9
8/28/97(R.T., Air)	4.3	5	5	5.6	12.3	13.7	13	13
10/30/97(4°C, N ₂)	3.8	4	4.7	3.8	14	15.5	14.7	14.8
10/30/97(4°C, Air)	3	4.1	3.7	4.7	12.6	14.9	14.3	14.4
10/30/97(R.T., N ₂)	1.5	3.4	3.5	3.6	13.8	15.1	14.6	14.4
10/30/97(R.T., Air)	1.5	3.6	2.2	3.1	12.7	14.7	14.8	14.4
1/12/98(4°C, N ₂)	3.2	4.1	3.3	3.4	7.3	11.1	9.5	9.5
1/12/98(4°C, Air)	1.5	3.8	3.9	3.4	7.7	10.8	10.2	10
1/12/98(R.T., N ₂)	0.1	1.4	0.7	0.7	10	10.8	11.1	10.4
1/12/98(R.T., Air)	0.4	1.6	1	0.4	9.9	11	10	10.4
4/30/98(4°C, N ₂)	0.08	4.3	4	5.3	5.1	12.3	12.3	12.1
4/30/98(4°C, Air)	1.5	3.6	4.4	4.5	5	11.6	11.8	11.9
4/30/98(R.T., N ₂)	0.0025	0.23	0.11	0.17	11.1	12.3	12.6	12.5
4/30/98(R.T., Air)	0.0015	0.21	0.063	0.007	11	12.4	12.3	11

G: glycerol S: sucrose PEG: PEG-3500 T: trehalose
 Glycerol is in PBS buffer (10%).
 Other formulations are in 10 mM-tris buffer with 0.15 M-NaCl and 1 mM-MgCl₂ (pH = 8.2).

Aqueous Formulation Set 2

Date (Temp.)	PFU x10 ⁹ /ml											
	AQF2-1	AQF2-2	AQF2-3	AQF2-4	AQF2-5	AQF2-6	AQF2-7	AQF2-8	AQF2-9	AQF2-10	AQF2-11	AQF2-12
9/25/97	2.8	2.8	2.8	3	2.8	2.8	2.7	2.8	2.7	3.3	3.1	2.7
11/05/97 (4 °C)	2.3	3.2	2.4	3.6	2.7	2	3.6	3.8	2.7	3	3.5	2.5
11/05/97 (R.T.)	2.2	0.1	2.4	2.7	2.1	2.1	3.2	2.1	3	3	3.4	2.9
12/12/97 (4 °C)	2.2	0.1	2.4	2.7	2.1	2.1	3.2	2.1	3	3	3.4	2.9
01/09/98 (r.t.)	1.2	<0.1	0.2	1.2	0.2	0.1	1.3	1.1	0.2	<0.1	2	1.1
3/27/98 (4 °C)	1.8	<0.1	1.9	2	<0.1	1.7	2	<0.1	2.6	2.9	2.6	1.8
3/27/98 (r.t.)	0.6	<0.1	<0.1	0.8	<0.1	<0.1	1	<0.1	<0.1	<0.1	1.1	0.7

Date (Temp.)	HPLC viral particles (x10 ¹⁰ /ml)											
	AQF2-1	AQF2-2	AQF2-3	AQF2-4	AQF2-5	AQF2-6	AQF2-7	AQF2-8	AQF2-9	AQF2-10	AQF2-11	AQF2-12
9/25/97	10.9	9.6	9.7	11.3	10.7	10.6	10.9	10.8	10.7	11.4	11.8	10.7
11/05/97 (4 °C)	7.9	7.6	8.7	8.8	8.9	7.5	8.6	9.1	9.2	10.3	11.2	9.6
11/05/97 (r.t.)	8.2	6.6	7.6	8.6	7.7	9.3	9	8	9.3	10.3	11.1	9.6
12/12/97 (4 °C)	6.7	1.5	8	6.9	5.2	7.5	7.5	6.1	7.6	8.8	7.3	7.7
12/17/97 (r.t.)	7	1.2	7	7.5	4.1	7.1	7	3	8.2	7.6	8.4	7.5
3/13/98 (4 °C)	5.6	N.D.	6.2	6.7	N.D.	6.5	6.8	N.D.	7.1	8	8.9	7.2
3/13/98 (r.t.)	6.2	N.D.	6.5	6.9	N.D.	7.3	6.8	N.D.	6.9	7.8	7.5	7.1

Aqueous Formulation Set 2

Excipients	AQF2-1	AQF2-2	AQF2-3	AQF2-4	AQF2-5	AQF2-6	AQF2-7	AQF2-8	AQF2-9	AQF2-10	AQF2-11	AQF2-12
mannitol (W%)	5	5	5				5	5	5	5	5	
sucrose (W%)				5	5	5	5	5	5	5	5	10
glycine (M)	0.25			0.25			0.25				0.25	0.25
arginine (M)		0.25			0.25			0.25			0.25	
urea (W%)			1			1			1		1	
peg (W%)										1	1	

Excipients are in 10 mM-tris buffer (pH = 8.2) which consists of 0.5% glycerol, 0.15 M-NaCl and 1mM MgCl₂.

The formulations are stored at 4 °C and room temperature under nitrogen.

FIG. 34

Aqueous Formulation Set 3

Date (temp.)	PFU x 10 ⁹				HPLC viral particles (x 10 ¹⁰ /ml)			
	F10-7	F10-8	F11-7	F11-8	F10-7	F10-8	F11-7	F11-8
10/3/97	2.2	3.3	2.1	2.8	12.1	12	11.8	12
11/6/97(-20 °C)	3.4	4	2.8	3.4	10.6	10.5	10.1	10.3
11/6/97(4°C)	3.5	3.6	4.3	2.8	10	9.7	9.9	10.3
1/15/98(-20 °C)	3.8	4.8	3.2	3.7	7.3	7.4	7.7	8
1/15/98(4 °C)	3.5	3.1	2.9	3.1	7.5	7.4	7.6	7.5

Excipients	F10-7	F10-8	F11-7	F11-8
mannitol(W%)	6	6	5	5
sucrose(W%)	7	8	7	8
HSA(W%)	0.5	0.5	0.5	0.5
glycerol(W%)	1	1	1	1
MgCl ₂ (mM)	1	1	1	1

FIG. 35

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Aqueous formulation set

Date(temp.)	PFU x 10 ⁹						
	AQF4-1	AQF4-2	AQF4-3	AQF4-4	AQF4-5	AQF4-6	AQF4-7
1/13/98	3	2.5	3.6	3.4	2.7	3.1	3.4
2/11/98 (4 °C)	2.5	3.2	3.3	2.9	2.6	2.9	2.6
2/11/98 (R.T.)	1.8	2.7	1.6	3.6	2.6	1.6	1.7
4/10/98 (4 °C)	2.2	2	2.6	3	2.4	1.9	2.2
4/10/98 (R.T.)	0.4	0.4	0.3	0.5	0.4	<0.1	1.1
7/24/98 (4 °C)	2.4	2.8	2.6	3.5	1.9	2.2	2.6
7/24/98 (R.T.)	0.002	0.005	0.006	0.005	0.005	0.005	0.001

Date(temp.)	HPLC Integrated Area						
	AQF4-1	AQF4-2	AQF4-3	AQF4-4	AQF4-5	AQF4-6	AQF4-7
1/13/98	8.7	10.9	11.5	11.1	9.5	9.7	11.3
2/16/98 (4 °C)	9.1	9.3	9.2	9.5	8.2	8.4	9.6
2/16/98 (R.T.)	6.8	9	9.5	9	8.7	8.4	9.3
4/10/98 (4 °C)	7.1	9.2	9.6	9.6	8.9	9.1	9.9
4/10/98 (R.T.)	7.5	9.5	10.1	9.7	8.9	8.9	9.5
7/24/98 (4 °C)	8.1	9.9	11.1	10.3	9.2	7.4	9.3
7/24/98 (R.T.)	7.3	3	10.7	8.9	10.4	10.45	3.5

Aqueous Formulation Set 4

Excipients	AQF4-1	AQF4-2	AQF4-3	AQF4-4	AQF4-5	AQF4-6	AQF4-7
mannitol(W%)	5	5	5	5	5	5	5
sucrose (W%)	5	5	5	5	5	5	5
Tween 80 (W%)		0.02	0.1	0.5			
Chap (W%)					0.02	0.1	0.5

Excipients are in 10 mM-tris buffer (pH = 8.2) which consists of 1% glycerol, 0.15 M-NaCl and 1 mM MgCl₂.

The formulations with virus are stored at 4 °C and room temperature under nitrogen.

FIG. 36

0920303-120198